3. Do ***not*** use hyphens (-), slashes (/), or blanks.
4. Do ***not*** enter product's name in lieu of the NDC.
5. Use capital letters for alphabetic data
6. See specific segment for additional special rules.

5.10.2.1 NDC Segment Specifications

Labeler Code

The National Drug Code Directory[1] defines a labeler as "...any firm that manufactures or distributes a drug product." The labeler code is assigned by the FDA.

a. Segment Name: Labeler Code
b. Field Length: 5 Characters
c. Positions/Columns: 12-16
d. Type: Alphanumeric
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

Product Code

The National Drug Code Directory defines the product code as the segment that "identifies a specific strength, dosage form, and formulation for a particular labeler." The product code is assigned by the labeler.

a. Segment Name: Product Code
b. Field Length: 4 Characters
c. Positions/Columns: 17-20
d. Type: Alphanumeric
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

---

[1] U.S. Department of Health and Human Services, Food and Drug Administration, *National Drug Code Directory*, Vol I, June 1995.

Package Size Code

The National Drug Code Directory defines package size code as the segment that "identifies trade package sizes." The package size code is assigned by the labeler.

a. Segment Name: Package Size Code
b. Field Length: 2 Characters
c. Positions/Columns: 21-22
d. Type: Alphanumeric or "**" for bulk finished (e.g., unpackaged bulk dosage units) or bulk raw material (e.g., powder or liquid)
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

5.10.2.2 Formatting Summary

Exhibit 5.8: NDC Formatting Summary, briefly describes the formatting specifications for the NDC. These specifications apply to controlled substance transactions reported on automated media as well as DEA Form 333 for the following products:

a. Bulk Raw Powder
b. Bulk Dosage Formulations
c. Bulk Solutions
d. Trade Packages

TYPE OF MATERIAL	LABELER CODE POSITIONS or COLUMNS: 12-16	PRODUCT CODE POSITIONS or COLUMNS: 17-20	PACKAGE CODE POSITIONS or COLUMNS: 21-22
Bulk raw powder; bulk dosage forms; bulk solutions	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros	**
Trade Packages	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros

Exhibit 5.8: NDC Formatting Summary

5.10.3 NDC Coding Examples

The NDC configuration for ARCOS reporting is composed of a 5-character Labeler Code, a 4-character Product Code, and a 2-character Package Code. When the NDC for a product ***does not*** conform to the configuration required under ARCOS, the following changes ***must*** be made in the configuration:

a. A leading zero ***must*** be added to the Labeler Code when this segment contains 4-characters.

b. A leading zero ***must*** be added to the Product Code when this segment contains 3-characters.

c. A leading zero ***must*** be added to the Package Size Code when this segment contains 1-character.

d. "**" ***must*** be placed in the Package Size Code segment when the product ***does not*** have a Package Size Code. The "**" indicates the product is in bulk form.

Transactions with incorrectly formatted NDC fields are rejected as erroneous and must be corrected and resubmitted. The exhibits in this section illustrate correct coding for the NDC field. Exhibit 5.9: Converting the NDC for a Non-bulk Product, illustrates how to convert an NDC for a non-bulk product to the format required by ARCOS. Exhibit 5.10: Converting the NDC for a Bulk Product, illustrates how to convert an NDC for a bulk product to the ARCOS format.

Fictitious Non-bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 - 12 (b) 12345 - 123 - 34 (c) 12345 - 1234 - 7

Converting To ARCOS NDC Configurations

a. 01234 - 1234 - 12
↑ leading zero added

b. 12345 - 0123 - 34
↑ leading zero added

c. 12345 - 1234 - 07
↑ leading zero added

Exhibit 5.9: Converting the NDC for a Non-bulk Product

Fictitious Bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 (b) 12345 - 123 (c) 12345 - 1234

Converting To ARCOS NDC Configurations

a. 01234 - 1234 - **
↑ "**" added
↑ leading zero added

b. 12345 - 0123 - **
↑ "**" added
↑ leading zero added

c. 12345 - 1234 - **
↑ "**" added

Exhibit 5.10: Converting the NDC for a Bulk Product

5.10.4 NDC Assignment

Identification of reportable controlled substances is always based on the Food and Drug Administration's National Drug Code (NDC). ***All*** *transaction records*, ***except*** for transaction codes 7, 8, and F ***must*** contain an NDC. Any *transaction record* with missing or invalid NDC will be rejected and must be corrected before being resubmitted. Contact the FDA at the address provided in Exhibit 5.11: FDA Address, for information about the National Drug Code.

Food and Drug Administration
Bureau of Drugs, Drug Listing Staff
5600 Fishers Lane
Center for Drug Evaluation & Research (CDER), HFD-95
Rockville, Maryland 20857
Telephone: (301) 594-1086 Hours: Monday-Friday 8:00am - 4:30pm EST/EDT

Exhibit 5.11: FDA Address

5.10.5 Submitting Labels

Pursuant to 21 CFR 1308.04, firms holding a DEA registration as a manufacturer ***must*** provide DEA (ARCOS) with information about each new product, new dosage form, or other unit form containing ***any*** quantity of controlled substance. This information ***must*** be submitted within 30 days ***after*** manufacturing begins. However, DEA (ARCOS) will also accept this information ***prior to*** the beginning of manufacturing. Two labels or other documents (e.g., Drug Listing Form, FDA 2657) which reflect the following information ***must*** be submitted:

a. The trade name, brand name, or other commercial name of the product;

b. The generic or chemical name and quantity of each active ingredient, including both controlled and non-controlled substances (indicate what information is a proprietary trade secret);

c. The National Drug Code assigned to the product, if any; and

d. The weight of controlled substance as follows:
(1) Finished Dosage Unit Products:
Grams or milligrams per dosage unit
(2) Bulk Products:
Grams or milligrams per gram of powder
Grams or milligrams per milliliter of liquid

Send this information to DEA (ARCOS). The address is listed on the contact information page at the front of this handbook. The Data Systems Unit (ARCOS)

strongly advises each manufacturer to send this information ***before*** submitting *transaction records* for their new products. A *transaction record* that does not have a matching NDC in the ARCOS NDC Dictionary is rejected as erroneous and must be resubmitted. Call the Data Systems Unit (ARCOS) to find out if the NDC information for your firm's new product has been added to the Dictionary.

All transactions for the new product that have occurred ***before*** the current reporting period, ***must*** be submitted as ***Late Transactions***. Otherwise, these transactions will be rejected as errors because their *transaction dates* are ***not*** within the current reporting period. See Section 7, Edit Listings, for Late Transaction instructions.

5.10.6 Pseudo NDC's

The pseudo NDC is a number developed by DEA (ARCOS) in consultation with the ARCOS registrant. A pseudo NDC may be requested from the DATA Systems Unit (ARCOS) when the NDC does not exist or is unavailable. This number enables ARCOS registrants to report transactions involving products for which an NDC is either unavailable or does not exist. Pseudo NDC's are ***not*** listed in the Food and Drug Administration's National Drug Code Directory.

5.10.6.1 Obtaining a Pseudo NDC

A written request on company letterhead must be made to the Data Systems Unit (ARCOS) for ***each*** product for which a pseudo NDC is needed. The request may be sent by mail or fax to the address or fax phone number listed on the contact information page at the front of the handbook and ***must*** contain the following information:

a. Manufacturer's Name and Address
b. Product Name and/or Generic Chemical Name
c. CSA Schedule and Drug Code
d. Controlled Ingredients and Concentration of Controlled Ingredients
e. Whether Controlled Ingredient is in Base or Salt Form
f. Package Size
g. Molecular Weight, Chemical Formula and Structure of Controlled Substance, if available.

5.10.7 Inner and Outer NDC Packages

A controlled substance product may have one NDC on an outer, larger package and a different NDC on the inner, smaller, individually-packaged units contained within the larger package. See Exhibit 5.12: Inner and Outer Packaging for an illustration. Either NDC may be used when reporting transactions and inventories. Care must be taken that the NDC ***corresponds*** to the product and package size being reported. A single NDC ***must never*** be used to identify two different package sizes of a product. The quantity reported will indicate the number of packages for that particular NDC.

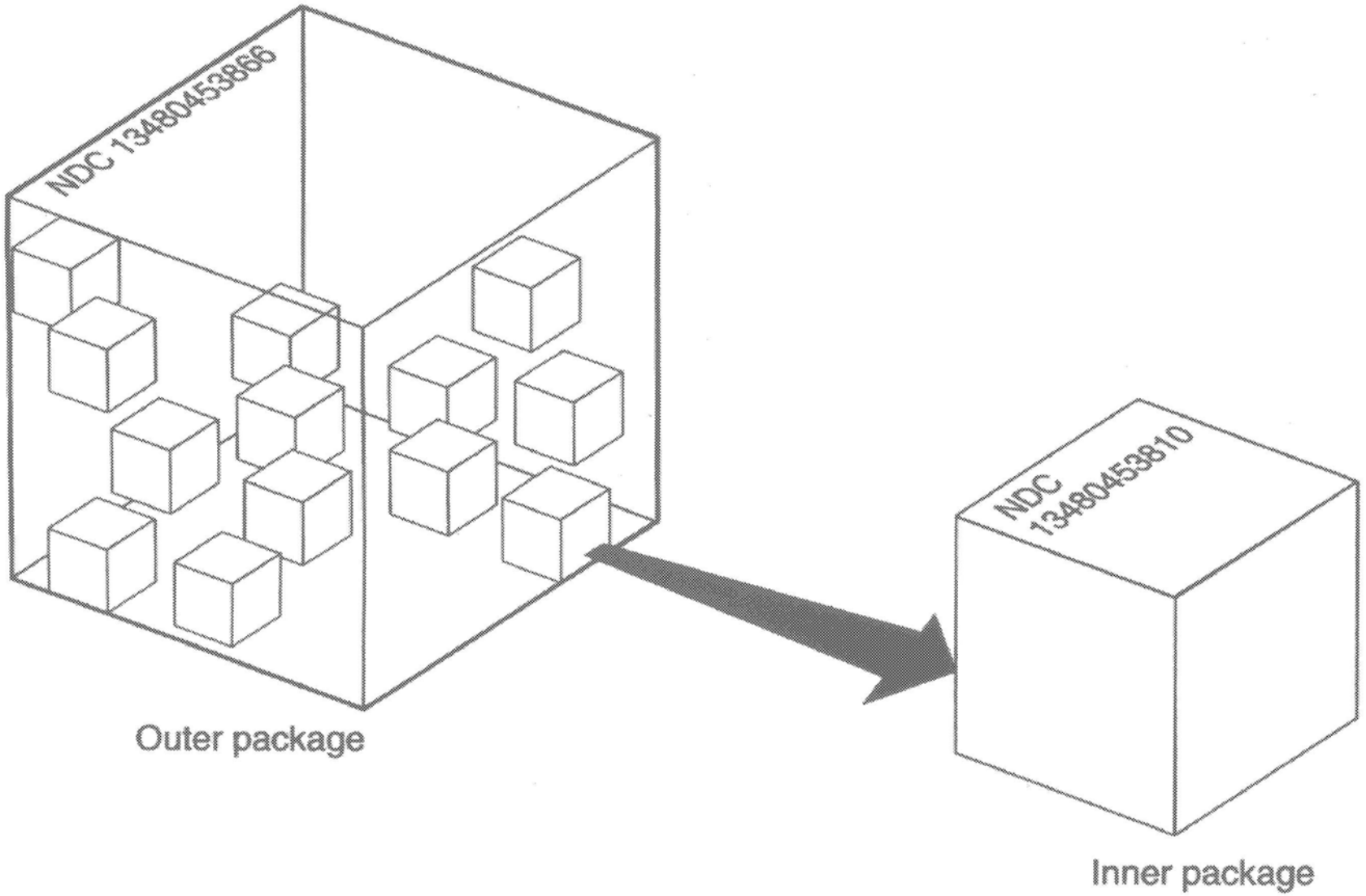


Exhibit 5.12: Inner and Outer Packages

5.11 QUANTITY

5.11.1 Definition: Quantity

The *quantity* field is a 6-digit (manual) or 8-digit (automated) numeric field containing the number of packages, weight, or volume being reported.

5.11.2 Specifications: Quantity

a. Field Number:	5
b. Field Name:	*quantity*
c. Field Length:	8 digits (automated) 6 digits (manual)
d. Positions/Columns:	23-30 (automated) 23-28 (manual)
e. Type:	Numeric
f. Special Rules:	

1. Mandatory entry, except for *transaction codes 7, 8, and F*.
   Note: For *transaction code F* 100 forms will be sent when the *quantity* field is left blank.

2. *Quantity* field (Field 5) and *unit* field (Field 6) are mandatory entries when the controlled substance is measured in weight or volume.

3. When the *unit* field is blank, the quantity entered corresponds to the number of packages being reported.

4. Right justify entry.

5. Blanks are ***not*** permitted. Insert leading zeros in columns to the left of the number entered.

6. Enter whole numbers only. Do not truncate. Do not round. Do not use decimals, commas, etc.

5.11.3 Discussion: Quantity

5.11.3.1 Converting Fractional (Decimal) Quantities

All quantities ***must*** be reported in whole numbers that have neither been truncated nor rounded. To report a fractional quantity, convert the amount to units that do not require fractions. For example, to report a bulk quantity of 417.29 grams, the quantity must be converted to milligrams prior to being reported (i.e., 417.29 grams would be reported as a quantity of "417290" with a *Unit* Code of 2 which indicates milligrams. The following examples illustrate the correct coding of fractional quantities for both automated and manual reports:

Automated Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		001790062**	00417290	2	AB1234567	940590027	012194		1000	000000001	E25

Manual Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		001790062**	417290	2	AB1234567	940590027		1000	40121	00002

5.11.3.2 Coding the Quantity Field

Exhibit 5.13: Quantity Field Entries, illustrates *quantity* field coding.

NDC Number	PACKAGE DESCRIPTION	QUANTITY FIELD ENTRY	DESCRIPTION OF ITEM(S) REPORTED
99999-9999-**	Bulk Tablets	00025000	25,000 Tablets
88888-8888-01	Bottle of 500 Tablets	00000001	1 bottle of 500 Tablets
88888-8888-01	Bottle of 500 Tablets	00000005	5 bottles * 500 Tablets/bottle
77777-7777-04	4 fl oz Bottle	00000001	1 bottle of 4 fl oz
77777-7777-04	4 fl oz Bottle	00000003	3 bottles of 4 fl oz each (total=12 fl oz)
66666-6666-01	5ml Ampule (injection)	00000001	5 ml
66666-6666-01	5ml Ampule (injection)	00000005	5 ampules of 5 ml each (total = 25 ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000001	1 box (50ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000010	10 boxes (500ml) 500 ml in 10 boxes of 50 ml each

Exhibit 5.13: Quantity Field Entries

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of the relationships between various types of products (e.g., bulk raw powder, bulk dosage units, trade packages) and the *quantity*, *unit*, and *strength* fields in the ARCOS *transaction record*.

5.11.3.3 Reporting Bulk Raw Material

The *unit* (Field 6) and *strength* (Field 11 automated, Field 10 manual) fields must always be completed when reporting a Bulk Raw Material (package code = **) by weight or volume. See example below:

Example:

A manufacturer reports the synthesis (production) of a Schedule II bulk drug in raw powder form, 100 % pure. This product is chemically identified as Ecgonine Hydrochloride, molecular weight 221.69, NDC designation 00179-0062-**. The manufacturer sells 3,365.45gms of the product to another ARCOS registrant on January 21, 1997 under DEA order form number 940590027. The following example illustrates the coding for this transaction.

Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		001790062**	03365450	2	AB1234567	940590027	012197		1000	000000001	E25

Note: Reported as milligrams

Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		001790062**	003365	3	AB1234567	940590027		1000	70121	00001
PP1234567	S		001790062**	000450	2	AB1234567	940590027		1000	70121	00002

5.11.3.4 Reporting Bulk Dosage Form Material

When a finished bulk item (e.g., drum of capsules or tablets) is reported, it is typically assigned a double asterisk (**) for its NDC package code. The *quantity* field contains the total number of bulk dosage units being reported. See example below:

Example:

Manufacturer reports the production of large quantities of capsules, each capsule contains 10mg of Schedule II d-amphetamine hydrochloride, molecular weight 171.67, NDC designation 00023-0124-**. Manufacturer sells 865,400 capsules to another ARCOS Registrant on May 22, 1997 under DEA order form number 940079038. The coding example for this transaction is illustrated below.

Automated Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		000230124**	00865400		AB1234567	940079038	052297			000000001	E25

Manual Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		000230124**	865400		AB1234567	940079038			70522	00001

5.12 UNIT CODE

5.12.1 Definition: Unit Code

The *unit code* is a single-character, alphanumeric field used in conjunction with the *quantity* and *strength* fields to specify, by weight or volume, the amount of an NDC product being reported.

5.12.2 Specifications: Unit Code

a. Field Number: 6
b. Field Name: *unit* code
c. Field Length: 1 Character
d. Position/Column: 31 (Automated)
29 (Manual)
e. Type: Alphanumeric
f. Special Rules:

1. Must be completed for all substances reported by weight or volume.

2. May also be used to modify the *Quantity* field by indicating dozens or thousands of packages.

5.12.3 Weight and Volume Unit Codes

The *unit code* field must be completed for all transactions reported by weight or volume by entering one of the following unit codes:

1 = micrograms
2 = milligrams
3 = grams
4 = kilograms
5 = milliliters
6 = liters

5.12.4 Optional Unit Codes

Transaction records reporting NDCs that consist of complete package or dosage units ***do not*** require a unit code. However, the following ***optional*** unit codes may be used to report dozens or thousands of packages or dosage units.

a. D = Dozens:
"D" indicates that the entry in the ***quantity*** field (Field 5) represents dozens of packages or dozens of dosage units.

b. K = Thousands:
"K" indicates that the entry in the ***quantity*** field (Field 5) represents thousands of packages or thousands of dosage units.

Example:

A sale of 10,000 units can be reported with a number 10 in the *quantity* field (Field 5) and a "K" in the *unit code* field (Field 6) as follows:

Automated Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)           (5)      (6)      (7)          (8)          (9)    (10) (11)      (12)       (13)
PP1234567   S      00065126810   00000010   K    AB1234567  940069028    081594              000000001   E25
```

Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)           (5)      (6)      (7)          (8)          (9)    (10)  (11-13)    (14)
PP1234567   S      00065126810   000010     K    AB1234567  940069028                       40815    00001
```

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of how to use *quantity*, *unit code*, and *strength* fields to report transactions involving NDC products in various forms, (e.g., bulk raw powder, bulk dosage units, trade packages).

5.13 ASSOCIATE REGISTRANT NUMBER

5.13.1 Definition: Associate Registrant Number

The *associate registrant number* is a 9-character field identifying the customer or supplier with which the transaction took place. For a sale enter the DEA registration number of the customer. For a purchase enter the DEA registration number of the supplier. Note: This field is labeled "Associate Registration Number" on DEA Form 333.

5.13.2 Specifications: Associate Registrant Number

a. Field Number: 7
b. Field Name: *associate registrant number*
c. Field Length: 9 Characters
d. Positions/Columns: 32-40 (Automated)
30-38 (Manual)
e. Type: Alphanumeric
f. Special Rules:
1. Use only DEA registration numbers.
2. Do not enter registrant's name.
3. Use only capital letters for alphabetic entries.

5.13.3 Discussion: Associate Registrant Number

The associate registrant number is required for ***each*** transaction that increases or decreases the ARCOS registrant's inventory. The reporting registrant number and the associate registrant number ***cannot*** be the same. The *associate registrant number* field is ***not*** completed when reporting the following transaction codes:

Schedule Change Inventory	Code 1
Year-end Inventory	Code 3
Year-end In-process Inventory	Code 4
Special Inventory	Code 5
No Year-end Inventory	Code 8
No Activity	Code 7
Forms Request	Code F
Thefts	Code T
Manufacturing Transaction Codes:	M, W, L, J, N, U, K and Q.

5.13.3.1 Transfers to Exempt Organizations

Organizations which are exempt from registration with DEA under the Controlled Substances Act may acquire products containing controlled substances from an ARCOS registrant. When an ARCOS registrant provides an exempt organization with such a product, the registrant reports this transaction by entering one of the codes listed in Exhibit 5.14: Exempt Organization Codes, in the *associate registrant number* field, Field 7. All entries ***must*** be ***left justified*** and in ***all capital (upper case) letters.*** Any remaining positions or columns ***must*** be blank.

Exempt Organization	Entry in Field 7 (Left Justified)
Civil Defense Officials	CIVILDEF
FDA or DEA Drug Recall	RECALL
Law Enforcement Official	OFFICER
Ocean Vessels Receiving Controlled Substances	VESSELS
Native American Church	NATIVE
Military, Public Health Service, Bureau of Prisons, or Coast Guard	MILITARY

Exhibit 5.14: Exempt Organization Codes

5.13.3.2 Transfers Within a Firm

The transfer of a controlled substance from one DEA registration to another ***within*** the ***same firm***, ***must*** be treated as a normal sale (*transaction code S*) and purchase (*transaction code P*). For example, when a transfer from a manufacturer's inventory to a distributor's inventory takes place, two transactions are reported:

a. A sale (*transaction code S*) is reported under the manufacturing registration number. The distributor's DEA registration number is entered into the *associate registrant number* field (Field 7).

b. A purchase (*transaction code P*) is reported under the distributor's registration number. The manufacturer's DEA registration number is entered into the *associate registrant number* field (Field 7).

5.13.3.3 Destruction of Reportable Items

Enter the registration number of the DEA area office in the *associate registrant number* field when reporting all destructions of controlled substances (*transaction code Y*. If necessary, contact the DEA area office or the Data Systems Unit (ARCOS) to obtain the DEA registration number. DEA Form 41, Registrants Inventory of Drugs Surrendered, ***must*** be completed and filed with the local DEA area office. Exhibit 5.6: DEA Form 41, contains a sample form.

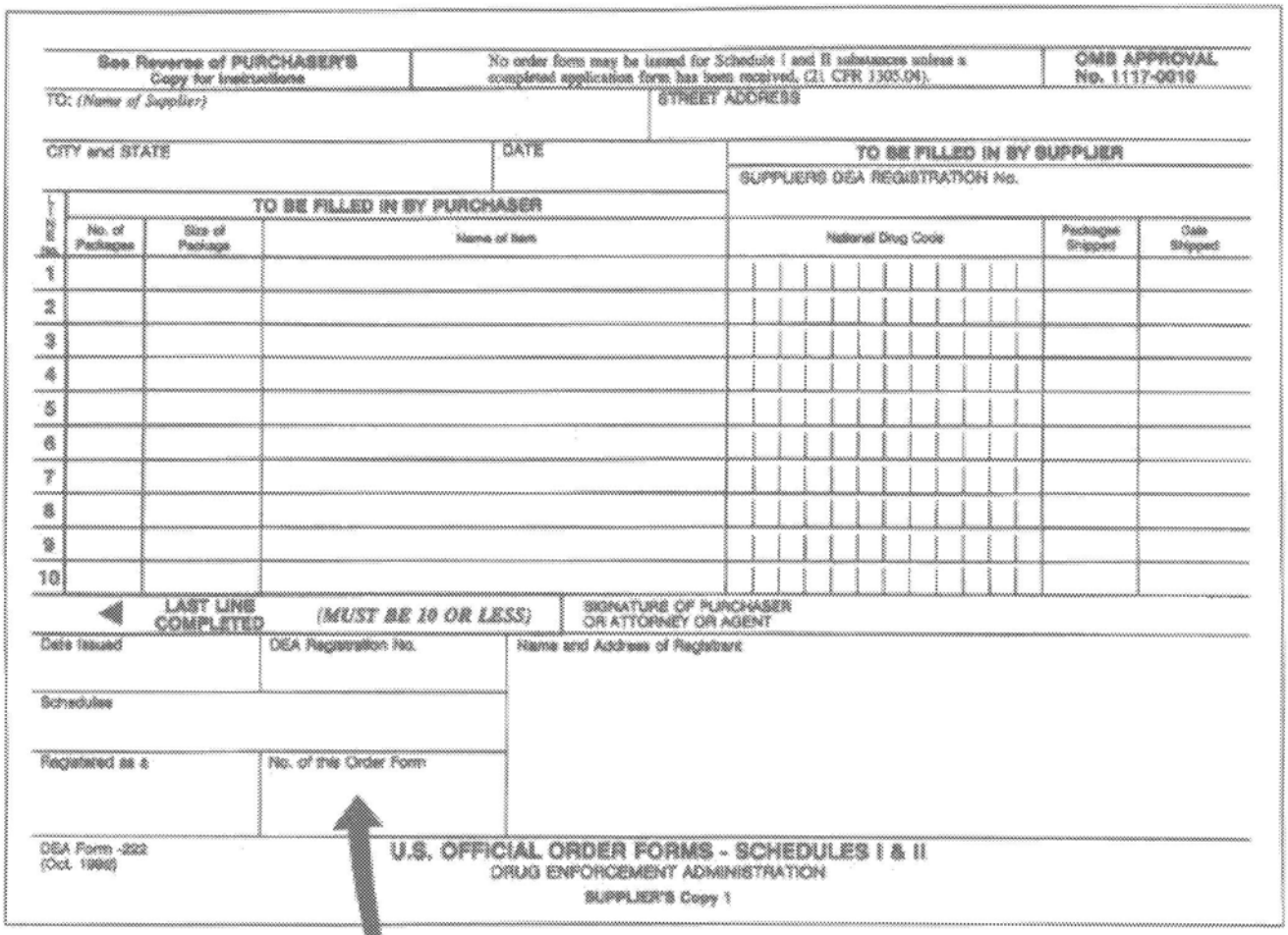
5.14 DEA ORDER FORM NUMBER

5.14.1 Definition: Order Form Number

The *DEA order form number* field is a 9-character field in which the number of the order form (DEA Form 222) is entered. This field is used only when Schedules I and II controlled substances are transferred. An order form is illustrated in Exhibit 5.15: DEA Form 222.

5.14.2 Specifications: Order Form Number

a. Field Number: 8
b. Field Name: *DEA order form number*
c. Field Length: 9 Characters
d. Positions/Columns: 41-49 (Automated)
39-47 (Manual)
e. Type: Alphanumeric
f. Special Rules:
    1. Mandatory for Schedules I and II
    2. Use Only Capital Letters for Alphabetic Data.



See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*

STREET ADDRESS

CITY and STATE

DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIER'S DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

Item No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT

Date Issued

DEA Registration No.

Name and Address of Registrant

Schedules

Registered as a

No. of this Order Form

DEA Form -222 (Oct. 1996)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Contains the number used in the DEA Order Form Number field (Field 8) of the ARCOS transaction record.

Exhibit 5.15: DEA Form 222

5.14.3 Discussion: Order Form Number

An order form, DEA Form 222, is required, pursuant to 21 CFR 1305, for transfers of Schedules I and II controlled substances, but an order form is ***not*** required for Schedule III narcotics. Leave the *DEA order form number* field blank when reporting Schedule 3 narcotics. Copy 2 of each DEA order form ***must*** be forwarded to the supplier's local DEA area office. Do ***not*** mail ***any*** copies of DEA Form 222 to DEA (ARCOS).

5.14.3.1 Manufacturer Recall

When a manufacturer recalls a reportable product, the transaction must be reported as a purchase (*transaction code P*). Those firms returning the product, that are alsoARCOS registrants, report a sale (*transaction code S*). When a schedule I or II controlled substance is recalled, DEA, Office of Diversion Control, may grant a limited exemption to the requirement for order forms. When such an exemption has been granted, the *DEA order form number* field (Field 8), must be completed with the word ***"RECALL"*** in ***all capital letters, left justified***. The remainder of the field must contain ***blank spaces***.

5.15 TRANSACTION DATE

5.15.1 Definition: Transaction Date

The *transaction date* is the ***actual*** date on which a reportable activity occurred. Exceptions are covered in Section 5.15.4, Discussion.

5.15.2 Specifications: Transaction Date

a. Field Number	9 (automated) 11-13 (manual)
b. Field Name:	*transaction date*
c. Field Length:	6 digits (Automated) 5 digits (Manual)
d. Positions/Columns:	50-55 (Automated) 60-64 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Automated and manual reporting have different formats.

5.15.3 Transaction Date Formats

Automated Format: **MMDDYY** (month, day, year)

Positions 50-51:	Month (01-12)
Positions 52-53:	Day (01-31)
Positions 54-55:	Year (last two-digits of the year 95, 96, etc.)

Coding Examples:

January 1, 1996:	010196
November 11, 1997:	111197

Manual Format: **YMMDD** (year, month, day)

Column 60:	Year (last digit of the year, 0-9)
Columns 61-62:	Month (01-12)
Columns 63-64:	Day (01-31)

Coding Examples:

January 1, 1996:	60101
November 11, 1997:	71111

5.15.4 Discussion: Transaction Date

A *transaction date* must be entered for all transactions. The *transaction date* ***must*** be the ***actual date*** on which the activity occurs. Except for manufacturing codes and delete, late, and adjustment transactions, the date of a transaction ***must never*** fall outside of the *reporting period* for the report being submitted.

Examples:

a. A *transaction record* with a June *transaction date* submitted with the July report is rejected unless it is a delete, late, or adjustment transaction (*action indicator* "D", "A", or "I").

b. Manufacturing activities associated with *transaction codes M, K, U, N, W, L, Q, and J* are reported as of the end of a quarter or the end of each year, even though these activities may actually have occurred on other dates during the year.

When using the duplicate sign (i.e. "=") to repeat a *transaction date* within a manual report, fields 11, 12 and 13 ***must*** be considered one field. In other words, the ***entire date must*** be the same when using the duplication sign. See Exhibit 5.2: Using the Duplicate Sign, Single Reporter or Exhibit 5.3: Using the Duplicate Sign, Central Reporter.

5.16 CORRECTION TRANSACTION

5.16.1 Definition: Correction Transaction

A Correction Transaction ***corrects*** a transaction that has been rejected by the data validation procedures. Rejected *transaction records* are listed in the Daily Transaction Processing Error Report.

5.16.2 Specifications: Correction Number (Formerly Lot Number)

a. Field Number:	10 (automated) 9 (manual)
b. Field Name:	*correction number* (formerly lot number)
c. Field Length:	8 digits
d. Positions/Columns:	56-63 (Automated) 48-55 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Mandatory when submitting one or more Correction Transactions.

5.16.3 Discussion: Correction Number

Each Correction Transaction is identified by a unique, sequential *correction number*. The system uses this number when reprocessing the corrected *transaction record*. The *correction number* is listed on the error report and ***must*** be entered into the *correction number* field. The Correction Transaction is a component of ARCOS error processing. Section 7.5, Correcting Transaction Records, contains a full discussion of error processing including specific instructions for using the Correction Transaction.

5.17 STRENGTH

5.17.1 Definition: Strength

The *strength* field is used to report three different kinds of data: (1) the ***purity*** of a ***bulk raw*** material (2) the ***fractional portion*** of a standard NDC package size or (3) the ***percentage*** by which a package ***exceeds*** a standard NDC package size.

5.17.2 Specifications: Strength

a. Field Number: 11 (automated)
10 (manual)
b. Field Name: *strength*
c. Field Length: 4 Digits
d. Positions/Columns: 64-67 (Automated) 56-59 (Manual)
e. Type: Numeric
f. Special Rules:

1. Mandatory entry for both ***bulk raw*** material and ***partial*** packages.
2. Fractional or Excess Package Size:
   (a) Decimal is ***implied*** and ***never*** coded.
   (b) Implied decimal point:
   automated: between positions 66 & 67
   manual: between columns 58 & 59
   (c) Decimal position:
   automated: position 67
   manual: column 59

5.17.3 Discussion: Strength

5.17.3.1 Strength Field: Bulk Raw Materials

The *strength* field ***must*** be completed when reporting a bulk raw material. All bulk raw materials and their level of purity are initially entered into the ARCOS drug ingredient dictionary. A *strength* field entry of 1000 (i.e. 100.0% purity) in a transaction involving a bulk raw controlled substance product indicates that the purity of the product being reported is the same as the corresponding NDC bulk raw material listed in the ARCOS drug ingredient dictionary. The *strength* field is required when reporting bulk raw materials. Any entry different from 1000 in this field indicates that the material being reported has a different purity than the bulk NDC listed in the ARCOS drug ingredient dictionary.

Example 1:

An NDC for a bulk raw material containing controlled substance with 90% purity is listed in the drug ingredient dictionary. The manufacturer sells a quantity of this material, unaltered, to a distributor, i.e. the manufacturer sells a powder containing 90% of a reportable controlled substance. Both manufacturer and distributor report this transaction (a sale for the manufacturer and a purchase for the distributor) with an entry of 1000 in the *strength* field, indicating that the purity of the product reported is equal to that of the product listed in the drug ingredient dictionary.

Example 2:

The same manufacturer as above (example 1) makes a batch of the same controlled substance mentioned above, but this time the purity of the batch is only 81%. The manufacturer wishes to sell some of this 81% pure controlled substance product using the NDC that is based on 90% purity. In order to do this, the manufacturer enters 0900 in the *strength* field, indicating that the purity of the material being reported is 90.0% of the 90% purity of the bulk NDC listed in the drug ingredient dictionary (.900 x .90 = .81).

5.17.3.2 Strength Field: Partial Packages

A partial package is an NDC package that has been opened and contains less than its original contents. To report a transaction with a partial package, enter the entire NDC in the NDC field (Field 4). Enter 1 with the correct number of leading zeroes in the *quantity* field (Field 5). In the *strength* field, enter the number of thousandths of the original contents of the NDC package that are being reported.

Example:

An NDC represents a bottle containing 100 LAAM hydrochloride tablets. An ARCOS registrant has an opened bottle of this NDC with 90 tablets remaining, 90% of the original package contents. To report this partial package, enter 1 with leading zeroes in the *quantity* field (Field 5) and "0900" in the *strength* field (Field 11 automated, Field 10 manual). The entry "0900" in the *strength* field indicates 90.0%. The decimal point in this percentage is implied, it is not to be coded. The following illustrations depict the correct automated and manual coding for reporting this example.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)          (5)     (6)     (7)          (8)         (9)    (10)  (11)     (12)      (13)
PP1234567    S      11326000301  00000001      AB1234567  940690028   081594        0900  00000001   E25
                                                                                                  ^------- Implied decimal
```

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)          (5)     (6)     (7)          (8)         (9)    (10)   (11-13)      (14)
PP1234567    S      11326000301  00000001      AB1234567  940690028          0900    40815       00001
                                                                                          ^------- Implied decimal
```

5.17.3.3 Strength Field: Combining Partial Packages

Two or more partial packages with the identical NDC may be reported as separate transactions or added together and reported as a single transaction, even when their combined contents are more than one complete package. The example below illustrates reporting ***two partial*** packages as a ***single*** transaction.

Example:

The standard NDC package size of Amytal tablets contains 100 tablets. An ARCOS Registrant needs to report two packages, each package containing less than 100 tablets. One package contains 90 Amytal tablets, while the other contains 25 Amytal tablets. The combined total of these two partial packages amounts to 115 tablets. This amount equals 115 percent of the standard package size.

To report 115 tablets as a single transaction, code a quantity of "1" in the *quantity* field (Field 5) and 1150 (115.0 percent of a full package) in the *strength* Field (Field 11 automated, Field 10 manual). Again, there is an ***implied*** decimal point between the two right-most positions in the *strength* Field.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)          (5)     (6)     (7)          (8)         (9)    (10)  (11)     (12)      (13)
PP1234567    S      10465592001  00000001      AB1234567  940690028   081594        1150  00000001   E25
                                                                                                  ^------- Implied decimal
```

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)          (5)     (6)     (7)          (8)         (9)    (10)   (11-13)      (14)
PP1234567    S      10465592001  00000001      AB1234567  940690028          1150    40815       00001
                                                                                          ^-------- Implied decimal
```

Refer to Appendix 4, Use of Quantity, Unit, and Strength Fields, for additional illustrations of ARCOS reporting relationships between various types of NDC products (i.e., bulk raw powder, bulk dosage units, trade packages) and the (a) *quantity*, (b) *unit code*, and (c) *strength* data fields in the ARCOS *transaction record.*

5.18 TRANSACTION IDENTIFIER

5.18.1 Definition: Transaction Identifier

The *transaction identifier* is a sequential number assigned by the reporting registrant to each *transaction record.*

5.18.2 Specifications: Transaction Identifier

a. Field Number:	12 (automated) 14 (manual)
b. Field Name:	*transaction identifier*
c. Field Length:	10 digits (automated) 5 digits (Manual)
d. Positions/Columns:	68-77(Automated) 65-69 (Manual)
e. Type:	Numeric

f. Special Rules:

1. The first *transaction identifier* within each report **must always** begin with the number one (1).

2. Each *transaction record* in a reporting period ***must*** have a unique *transaction Identifier.*

3. Leading zeroes must be included.

4. The original *transaction identifier* is repeated when submitting a correction, an adjustment, or a deletion.

5. A Late Transaction uses the next sequential *transaction identifier* from the initial report submitted.

5.18.3 Discussion: Transaction Identifier

The *transaction identifier* field for *transaction records* submitted by central reporters may use one of two configurations:

a. Continuous Sequence:
Transaction records may be numbered in a continuous sequence.

b. Separate Sequences
Transaction records for each reporting registrant may be numbered in separate sequences.

Example: Continuous Sequence

A central reporter submits a report for itself and two subsidiaries containing a total of 150 transactions. These records may be numbered sequentially and continuously "1" through "150."

Example: Separate Sequences

A central reporter submits a report for itself and three subsidiaries containing a total of 400 transactions. These records may be numbered "1" to "125" for the central reporters own registration number, "1" to "50" for the first subsidiary, "1" to "200" for the second subsidiary and "1" to "25" for the third subsidiary.

5.19 DOCUMENT IDENTIFIER

5.19.1 Definition: Document Identifier

The *document identifier* is used to distinguish reports submitted on magnetic media (i.e., diskette or tape) from reports submitted on DEA Form 333 coding sheets. The *document identifier* appears only in automated *transaction records*.

5.19.2 Specifications: Document Identifier

a. Field Number: 13
b. Field Name: *document identifier*
c. Field Length: 3 Characters
d. Positions: 78-80
e. Type: Alphanumeric
f. Special Rules:
    1. "E25" is the only acceptable entry.
    2. Only in automated *transaction records*.

5.19.3 Discussion: Document Identifier

No additional discussion.

6

SECTION 6.0

MANUFACTURING ACTIVITIES

6.1 GENERAL

Section 6 contains ARCOS manufacturing instructions as they apply to the reporting of narcotics and psychotropics. The manufacturing activities and specific transaction code designations are identified and described in this section as follows: CODES 3, 4, W, M, L, J, K, Q, N, U. The narcotic and psychotropic drug statistics derived from these manufacturing transaction codes are used primarily for fulfillment of United States treaty obligations. The United States is a signatory to the (a) Single Convention on Narcotic Drugs, 1961 and (b) Convention on Psychotropic Substances, 1971, and as such is required to provide yearly statistics to the United Nations International Narcotics Control Board.

6.1.1 Reporting by Bulk and Dosage Form Manufacturers

Manufacturers of bulk powders, bulk dosage formulations and/or dosage package size formulations of any Schedule I & II controlled substance, any narcotic controlled substance in Schedule III, and any listed psychotropic controlled substances in Schedules III and IV must report those manufacturing activities as set forth in this section. The manufacturers of controlled substances in Schedules I and II and/or any narcotic in Schedule III are also required to report on those applicable transaction activities relating to inventories, acquisitions and dispositions as set forth in this handbook.

6.1.2 Reporting by Packers, Repackers and Relabelers

Manufacturers registered for activities such as packing, repacking and relabeling of controlled substances in Schedules I and II and/or any narcotic in Schedule III are not required to report

the actual packing, repacking or relabeling manufacturing activity, but must report other manufacturing activities as set forth in this section, as well as activities that relate to inventories, acquisitions, and dispositions as set forth in this handbook.

6.1.2.1 Definitions:

The following definitions are provided for clarification.

a. A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each (i.e., repacker).

b. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e, relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. See the following example and reporting scenario:

6.1.2.2 Scenario for Repackaging and Relabeling

A manufacturer purchases 50,000 codeine phosphate tablets (NDC 00034-4156-**). The manufacturer subsequently repackages and relabels to package size of 50 per carton (NDC 00036-4156-01) and package size of 100 per carton (NDC 00036-4156-02). On June 23, 1997, 50 and 150 cartons of NDC products 00036-4156-01 and 00036-4156-02, respectively, are sold to a distributor.

6.1.2.3 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	P		000344156**	00050000		PP0233560	940690023	062397			0000000001	E25
PP1234567	S		00036415601	00000050		PM0105444	940690023	062397			0000000002	E25
PP1234567	S		00036415602	00000150		PM0105444	940690023	062397			0000000003	E25

6.1.2.4 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	P		000344156**	050000		PP0233560	940690023			70623	00001
PP1234567	S		00036415601	000050		PM0105444	940690023			70623	00002
PP1234567	S		00036415602	000150		PM0105444	940690023			70623	00003

6.1.3 Reporting Non-Manufacturing Activities

All non-manufacturing activities (i.e., those not described in Section 6 of this handbook) such

as acquisition transactions (i.e., codes P, R, G, V), disposition transactions (i.e., codes S, Y, T, Z,), inventory transactions (i.e., codes 1,3,5,8) and miscellaneous transactions (i.e., codes 7, F, X) will continue to be reported on the dates that the transaction actually occurred consistent with the format described in this handbook.

6.1.4 Manufacturing Reporting Guidelines

- Manufacturing activities (i.e., *transaction codes M, U, K, L, Q, J, W, and N*) may be reported quarterly or annually. In either instance the date of the manufacturing transaction activity must be shown as the last day of the calendar year or quarter being reported.

- When reporting specific manufacturing transaction codes identified in Section 6, the quantities of NDC products being reported may be expressed (a) by listing the amount of the NDC product containing the controlled substance in its original salt or derivative form (i.e., not converted to anhydrous base drug) or (b) in terms of anhydrous base controlled substance utilizing the salt conversion factors listed in Appendix 3. The ARCOS system will automatically convert all salt/derivative formulations to appropriate quantities of anhydrous controlled substance.

- If the manufacturer chooses to report in terms of anhydrous base substance, the NDC product being reported on the *transaction record* must reflect the anhydrous base substance and not the specific salt/derivative form.

- Please refer to the reporting matrix at Appendix 1 for automated reporting and at Appendix 2 for manual reporting as an aid in identifying the required fields of information for each acquisition, disposition, inventory, and manufacturing activity transaction code.

6.2 NARCOTICS

The specific types of ARCOS manufacturing activities required for all narcotics listed in Schedules I through III are:

a. **Quantity manufactured**.

This means the amount in grams of base weight of all reportable controlled substances manufactured or synthesized by the manufacturer. Base weight conversion factors are listed in Appendix 3.

b. **Quantity used for the manufacture of other preparations**.

This means the amount in grams of base weight of each controlled substance in

Schedules I and II used to produce (a) Schedule III, IV, or V preparations or (b) exempt chemical preparations (21 CFR 1308.23), or exempted prescription products (21 CFR 1308.32).

c. **Quantity held in stock on 31 December**.

This means the amount in grams of base weight of all reportable controlled substances that physically exists in the manufacturer's location as of December 31 of the reporting year. It is also essential that the manufacturer include that quantity of each controlled substance that is considered to be **in-process** material (i.e. that quantity of controlled substance which is not, at the time of the year-end inventory, in the bulk or finished dosage formulation stage). In-process inventory are those quantities of reportable drug stocks which are not included in a manufacturer's calculation of finished/dosage form inventory.

6.2.1 Manufacturing Narcotics

Code "M" is the *transaction code* to be used by all narcotic manufacturers that synthesize a controlled substance to produce the following: (a) bulk powder form, (b) large bulk quantities of formulated, but non-packaged tablets, capsules, or vials or large quantities (e.g., drum) of drugs in solution with known concentration. An "M" transaction is to be reported at the end of each calendar year or quarter and shall reflect the total quantity of each bulk substance produced during that reporting period. Individual "M" transactions for the same narcotic during the reporting period may be consolidated and reported as one "M" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "M" transaction. Note, also, that for each unique NDC number, *transaction code M* must be reported once at the end of each calendar quarter or annually on December 31.

For various reasons, if a quantity of controlled substance previously reported as manufactured must be returned to the production process (i.e. reworked), the only ARCOS data reported is the overall ***net change*** to the previously reported controlled substance.

a. If ***less*** is produced after reworking than was previously reported, an "N" transaction code (i.e. non-recovered waste) would be reported reflecting the ***difference*** in weight of controlled substance between the new manufactured data and the previously reported manufactured data. Do not report the newly manufactured product; report only the difference (i.e. code "N").

b. If ***more*** is produced after reworking than was previously reported, the

additional quantity of controlled substance in excess of the previously reported controlled substance is to be reported as an "M" transaction.

c. If no net change occurs with reworked material, nothing need be reported.

6.2.1.1 Manufacturing Scenario for "M" Transaction Code

On December 15, 1997, a manufacturer synthesized a total of 1,624,669 grams of thebaine (NDC 00406-1686-**), 100% pure.

6.2.1.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	M		004061686**	01624669	3			123197		1000	0000001234	E25

6.2.1.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	M		004061686**	001624	4				1000	71231	01234
PP1234567	M		004061686**	000669	3				1000	71231	01235

***NOTE**: Since the ARCOS Manual Report layout allows for only 6 positions in the quantity field, the manufacturer submits two transactions; one for the manufacture of 1,624 kilograms (unit=4) and the other for 669 grams (unit=3).*

6.2.2 Narcotics: Quantity Used To Produce Preparations

The "K" *transaction code* represents the mechanism used to identify the amount of narcotics used to produce Schedule III, IV, V, or exempt chemical preparations.

The "K" *transaction code* ***will*** be reported quarterly or annually on December 31 for each narcotic listed in Schedules I & II used to produce (1) Schedule III, IV & V preparations and/or (2) exempt chemical preparations (21 CFR 1308.23).

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "K" transaction. Note, also, that for each unique NDC number, *transaction code K* must be reported once at the end of each calendar quarter or annually on December 31.

6.2.2.1 Manufacturing Scenario for "K" Transaction Code

On April 30, 1997, a manufacturer utilized 10,134 milligrams of the bulk schedule II narcotic, hydrocodone bitartrate (NDC 00019-1582-**), 99% pure to produce a Schedule III, IV, V product or an exempt chemical preparation containing the same narcotic (i.e., hydrocodone

bitartrate).

6.2.2.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	K		000191582**	00010134	2			123197		0990	0000001000	E25

6.2.2.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	K		000191582**	010134	2				0990	61231	01000

6.2.3 Narcotics: Quantity Used to Produce a Different Narcotic

The United States is required to provide statistics reflecting the quantities of specific narcotics utilized to generate chemically different ARCOS reportable narcotic substances. *Transaction code U* is used to report this narcotic conversion data. The following list represents a few examples of the specific narcotics to be reported to the UN.

Substance Used	Substance Obtained
Opium	Morphine, Codeine, Thebaine
Codeine	Dihydrocodeine, Hydrocodone
Ecgonine	Cocaine
Thebaine	Codeine, Dihydrocodeine, Hydrocodone, Oxycodone, Thebacone, Buprenorphine, Nalbuphine, Naloxone, Naltrexone

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "U" transaction. Note, also, that for each unique NDC number, *transaction code U* must be reported once at the end of each calendar quarter or annually on December 31.

6.2.3.1 Manufacturing Scenario for "U" Transaction Code

On April 31, 1997, a manufacturer utilized 50kg of bulk codeine sulfate powder (NDC 00045-0974-**), 99% pure to produce 200 gm of dihydrocodeine, 98% purity. This scenario would require the submission of a "U" transaction to report the codeine sulfate utilization and a corresponding "M" transaction to report the manufacture of the narcotic substance which was produced (i.e., dihydrocodeine).

6.2.3.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers):

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	U		000450974**	00000050	4			123197		0990	000000001	E25

```
PP1234567  M        000087803**     00000200    3              123197          0980    000000002   E25
```

6.2.3.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
   (1)     (2)  (3)      (4)            (5)         (6)   (7)   (8)      (9)      (10)      (11-13)      (14)
PP1234567  U        000450974**     000050        4                              0990      71231        00001
PP1234567  M       000087803**     000200        3                              0980      71231        00002
```

6.2.4 Inventory Held in Stock on 31 December

The "3" *transaction code* is used to report the annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR 1304.33. Inventories for all physically stored bulk or dosage form controlled substances are reported by a code "3" transaction. This inventory is to be taken at the close of business on December 31 of the reported year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end in-process inventory for all reportable controlled substances by manufacturer in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type (i.e., in-process) are to be reported with a *transaction code 4*. The in-process manufacturing inventory is to be taken at the close of business on December 31 of the reported year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 4.***

Please refer to Appendices 1 and 2 for additional information on the required fields of information for *transaction codes* "3"and "4".

6.2.5 Manufacturing Scenarios for "3" and "4" Transaction Codes

On December 31, 1997, a manufacturer reported a year end inventory for (a) 53,967 grams of 100% pure bulk methadone hydrochloride (NDC 00019-1510-**), (b) 158,000 filled bottles of dronabinol capsules (NDC 00051-0021-01), (c) 89,000 ml of morphine sulfate solution (NDC 00054-3751-**) and (d) 365,000 liters of morphine sulfate solution (NDC 00186-0686-**) contained in the in-process production stream.

6.2.5.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
   (1)     (2)  (3)      (4)            (5)         (6)   (7)   (8)      (9)      (10)  (11)      (12)         (13)
PP1234567  3        000191510**     00053967    3              123197          1000    0000000001   E25
PP1234567  3        00051002101     00158000                   123197                  0000000002   E25
PP1234567  3        000543751**     00089000    5              123197                  0000000003   E25
PP1234567  4        001860686**     00365000    6              123197                  0000000004   E25
```

6.2.5.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)		(14)
PP1234567	3		000191510**	053967	3				1000	71231	00001	
PP1234567	3		00051002101	158000						71731		00002
PP1234567	3		000543751**	089000	5					71231		00003
PP1234567	4		001860686**	365000	6					71231		00004

6.3 PSYCHOTROPICS

The specific types of manufacturing activities required for all psychotropic substances listed in Schedules I through IV are:

a. **Quantity Manufactured**.

This means the amount of base weight controlled substance (in grams) manufactured or synthesized by the manufacturer. Base weight conversion factors are listed in Appendix 3.

b. **Quantity used for the manufacture of non-psychotropic substances**.

This means the quantity of bulk controlled substance used in a calendar quarter or year to produce a non-psychotropic substance. A non-psychotropic substance is any substance not listed in any Schedule of the 1971 Psychotropic Convention.

c. **Quantity used for the manufacture of exempt preparations**.

This means the quantity of bulk controlled substance used in a calendar quarter or year to produce (a) Excluded non-narcotic substances (21 CFR 1308.21), (b) Exempt chemical preparations (21 CFR 1308.23), or (c) Exempted prescription products (21 CFR 1308.31).

d. **Quantity held in stock on 31 December**.

This means the amount (in grams) of base weight of all reportable controlled substances that physically exists in the manufacturers' location as of December 31 of the reporting year. It is also essential that the manufacturer include that

quantity of each controlled substance that is considered to be in-process material (i.e., that quantity of controlled substance which is not, at the time of the time of the year-end inventory, in the bulk or finished dosage formulation stage).

6.3.1 Psychotropic Drugs

The psychotropic controlled substances for which manufacturing activities ***must*** be reported are as follows (shown by CSA Schedule and covered in 21 CFR 1304.33).
Manufacturers are not required to report acquisition or disposition transactions for any of the psychotropic controlled substances in Schedules III and IV listed below.

SCHEDULE I SUBSTANCES

(1) Diethyltryptamine
(2) Dimethyltryptamine
(3) Lysergic acid diethylamide(LSD, LSD-25)
(4) Mecloqualone
(5) Mescaline
(6) Psilocyn
(7) Psilocybin
(8) 4-methyl-2,5-dimethoxyamphetamine(STP)
(9) Tetrahydrocannabinols(THC, certain isomers)
(10)Ethylamine analogue of PCP(PCE)
(11)Pyrrolidine analogue of PCP(PCPy)
(12)Thiophene analogue of PCP(TCP)
(13)Methaqualone

SCHEDULE II SUBSTANCES

(1) Amobarbital
(2) Amphetamines
(3) Methamphetamine
(4) Secobarbital
(5) Methylphenidate
(6) Pentobarbital
(7) Phenmetrazine

(8) Phencyclidine (PCP)
(9) Glutethimide

SCHEDULE III SUBSTANCES

(1) Benzphetamine
(2) Cyclobarbital
(3) Methyprylon
(4) Phendimetrazine

SCHEDULE IV SUBSTANCES

(1) Barbital
(2) Diethylpropion (Amfepramone)
(3) Ethchlorvynol
(4) Ethinamate
(5) Lefetamine (SPA)
(6) Mazindol
(7) Meprobamate
(8) Methylphenobarbital
(9) Phenobarbital
(10)Phentermine
(11)Pipradrol

6.3.2 Manufacturing Psychotropics

Code "M" is the transaction code to be used by all psychotropic manufacturers actually synthesizing a controlled substance to produce (1) a bulk powder form, (2) large bulk quantities of formulated but ***non-packaged*** tablets, capsules, vials or (3) large quantities (e.g.,drum) of drugs in solution with known concentration. Those bulk manufacturers synthesizing a ***new*** chemical substance or producing a ***new*** chemical via an extraction process are to report this activity using an "M" *transaction code* designation.

An "M" transaction is to be reported each calendar quarter or year and shall reflect the total

quantity of each bulk chemical produced during the *reporting period*. Individual "M" transactions for the same psychotropic substance during the reporting period may be consolidated and reported as one "M" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "M" transaction. Note, also, that for each unique NDC number, *transaction code M* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.2.1 Manufacturing Scenario for "M" Transaction Code

On June 30, 1997, a manufacturer synthesized a total of 4,669 grams of 3,4-methylenedioxyamphetamine (MDA) (NDC 00073-1002-**), 97% pure.

6.3.2.2 ARCOS Automated Report: (number in parenthesis indicate data field entries)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	M		000731002**	00004669	3			123197		0970	0000001234	E25

6.3.2.3 ARCOS Manual Report: (number in parenthesis indicate data field entries)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	M		000731002**	004669	3				0970	641231	01234

6.3.3 Psychotropics: Quantity Used to Make Non-Psychotropic Substances

The "U" transaction code is the mechanism employed to capture the conversion of the listed psychotropics to a non-psychotropic substance. The "U" transaction code will be used to report this activity on a quarterly or annual basis. Individual "U" transactions for the same psychotropic substances during the reporting period may be consolidated and reported as one "U" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "U" transaction. Note, also, that for each unique NDC number, *transaction code U* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.3.1 Manufacturing Scenario for "U" Transaction Code

On September 30, 1997, a manufacturer purchased 75 kg of bulk levmethamphetamine base powder (NDC 00079-1470-**), 99% pure from another manufacturer under DEA order form number 942356780 and subsequently utilized 50 kg of bulk levmethamphetamine (NDC 00079-1470-**), to produce a non-psychotropic substance (i.e., selegiline). This scenario would require the submission of a "P" transaction to report the purchase of the bulk levmethamphetamine and a corresponding "U" transaction to report the levmethamphetamine utilization.

6.3.3.2 ARCOS Automated Report: (number in parenthesis indicate data field entries)

```
  (1)      (2) (3)    (4)          (5)     (6)   (7)          (8)        (9)  (10) (11)    (12)     (13)
PP1234567 P    000791470** 00000075  4  PG0208947  942356780 093097    0990  000001234  E25
PP1234567 U    000791470** 00000050  4                        123197    0970  000001235  E25
```

6.3.3.3 ARCOS Manual Report: (number in parenthesis indicate data field entries)

```
  (1)      (2) (3)     (4)          (5)    (6)    (7)          (8)      (9) (10)    (11-13)     (14)
PP1234567  P     000791470** 000075  4   PG0208947  942356780    0990      70930      01234
PP1234567  U     000791470** 000050  4                          0990      71231      01235
```

6.3.4 Psychotropics: Quantity Used to Manufacture Exempt Preparations

Transaction code K is used to report manufacturing activity involving the utilization of selected psychotropics to produce (1) exempt chemical preparations (21 CFR 1308.23), (2) excluded nonnarcotic substances (21 CFR 1308.21) or (3) exempted prescription products. (21 CFR 1308.32). The "K" *transaction code* will be used to report this activity on a quarterly or annual basis. Individual "K" transactions for the same psychotropic substances during the reporting period may be consolidated and reported as one "K" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "K" transaction. Note, also, that for each unique NDC number, *transaction code K* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.4.1 Manufacturing Scenario for "K" Transaction Code

On March 31, 1997, a manufacturer utilized 4 milligrams of the bulk tenocyclidine hydrocloride powder (NDC 00079-0248-**), 99% pure to produce (a) an exempt chemical preparation containing the same psychotropic (i.e., tenocyclidine hydrochloride); (b) utilized 100 micrograms of bulk glutethimide powder (NDC 00079-0024-**) 98% pure to produce an exempted prescription product and utilized 250 grams of bulk meprobamate powder (NDC 00436-0809-**), 95% pure to produce an excluded substance.

6.3.4.2 ARCOS Automated Report: (TENOCYCLIDINE HCL) (numbers in parenthesis indicate data field entries).

```
  (1)      (2) (3)    (4)          (5)      (6)  (7)  (8)  (9)    (10)    (11)      (12)       (13)
PP1234567 K     000790248**  00000004   2          123197      0990    0000001234    E25
```

6.3.4.4ARCOS Automated Report:
(GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
   (1)      (2)  (3)    (4)          (5)    (6)   (7)    (8)   (9)       (10)     (11)       (12)        (13)
PP1234567  K       000790024**  00000100  1                 123197             0980     0000001234     E25
```

6.3.4.5 ARCOS Manual Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data

field numbers)

```
  (1)     (2) (3)     (4)          (5)     (6)  (7)  (8)  (9)     (10)   (11-13)      (14)
PP1234567  K      000790024**  000100   1                        0980   71231       01234
```

6.3.4.6 ARCOS Automated Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
  (1)     (2) (3)     (4)          (5)     (6)  (7)  (8)  (9)     (10)   (11)      (12)       (13)
PP1234567  K      0004360809** 00000250  3                   123197         0950   0000001234  E25
```

6.3.4.7 ARCOS Manual Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
  (1)     (2)  (3)     (4)          (5)     (6)  (7)  (8)  (9)     (10)   (11-13)      (14)
PP1234567  K      004360809**  000250   3                        0950   71231       01234
```

6.3.5 Inventory Held in Stock on 31 December

Transaction code 3 is used to report annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR §1304.33. Inventories for all physically stored, bulk or dosage form controlled substances are reported by a code "3" transaction. This inventory is to be taken at the close of business on December 31 of the reporting year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end ***in-process*** inventory for all reportable controlled substances by manufacturers in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type (***i.e., in-process***) are to be reported with a *transaction code 4*. The ***in-process***

6.3.4.3 ARCOS Manual Report: (TENOCYCLIDINE HCL) (numbers in parenthesis indicate data field numbers)

```
  (1)      (2) (3)     (4)          (5)    (6) (7) (8)    (9)    (10)  (11-13)      (14)
PP1234567  K      000790248**  000004  2                        0990  71231      01234
```

6.3.4.4 ARCOS Automated Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
  (1)      (2) (3)     (4)          (5)    (6) (7) (8)   (9)   (10)   (11)       (12)       (13)
PP1234567  K      000790024** 1  00000100 1         123197     0980     0000001234   E25
```

6.3.4.5 ARCOS Manual Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
  (1)      (2) (3)     (4)          (5)    (6) (7) (8)   (9)    (10)  (11-13)      (14)
PP1234567  K      000790024**  000100  1                         0980  71231      01234
```

6.3.4.6 ARCOS Automated Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
  (1)      (2) (3)     (4)          (5)    (6) (7) (8)   (9)    (10)   (11)     (12)       (13)
PP1234567 K      004360809**  00000250 3         123197      0950 0000001234   E25
```

6.3.4.7 ARCOS Manual Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
  (1)      (2) (3)     (4)          (5)    (6) (7) (8)    (9)    (10)  (11-13)      (14)
PP1234567  K      004360809**  000250  3                         0950  71231      01234
```

6.3.5 Inventory Held in Stock on 31 December

Transaction code 3 is used to report annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR §1304.33. Inventories for all physically stored, bulk or dosage form controlled substances are reported by a code "3" transaction. This inventory is to be taken at the close of business on December 31 of the reporting year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end ***in-process*** inventory for all reportable controlled substances by manufacturers in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type (***i.e., in-process***) are to be reported with a *transaction code 4*. The ***in-process***

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "N" transaction. Note, also, that for each unique NDC number, *transaction code N* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "N" Transaction Code

From February 1 through June 30, 1997, a manufacturer's journal on non-recoverable waste (CODE-N) was maintained and updated at the end of each day, reflecting a total of 250 grams of non-recoverable waste associated with the manufacture of bulk raw hydrocodone bitartrate powder (NDC 00373-4461-**) and a non-recoverable waste of 38 grams of bulk raw meprobamate powder (NDC 00074-5434-**).

6.4.1.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PG1234567	N		003734461**	00000250	3			123197		1000	0000000001	E25
PG1234567	N		000745344**	00000038	3			123197		1000	0000000002	E25

6.4.1.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	N		003734461**	000250					1000	61231	00001
PG1234567	N		000745344**	000038	3				1000	61232	00002

6.4.2 Recovered Waste (Code W)

During the manufacturing processes of controlled narcotics and psychotropics, some bulk raw powder or bulk dosage form products may accumulate or be held in stock for later processing. A narcotic or psychotropic substance accumulated during the manufacturing process and held for later processing is recovered waste. In other instances, this residue cannot be reprocessed, but will be returned to storage (reported as recovered waste), accumulated for a period of time, and then destroyed. Any waste returned to inventory is considered recovered waste. Code "W" is the transaction code used to reflect this type of manufacturing activity. The "W" transaction activity must be reported quarterly or annually for each ARCOS reportable narcotic or psychotropic substance. Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "W" transaction. Note, also, that for each unique NDC number, *transaction code W* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "W" Transaction Code:

From May 1 through August 30, 19977 a manufacturer's journal on recoverable waste (CODE-W) was maintained and updated at the end of each day, reflecting measurable losses of hydrocodone bitartrate capsules (NDC 00404-0016-**) and bulk phenobarbital raw powder (NDC 00019-6584-**) due to spillage, contamination, and/or machine residue accumulation. The following entries report the losses due to spillage (552 capsules) and machine residue accumulation (1250 GM raw powder).

6.4.2.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11	(12)	(13)
PG1234567	W		004040016**	00000552				123197			0000000001	E25
PG1234567	W		000196584**	00001250	3			123197	1000		0000000002	E25

6.4.2.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	W		004040016**	000552						71231	00001
PG1234567	W		000196584**	001250	3				1000	71232	00002

6.4.3 Reversing (Code L)

Manufacturers involved in the normal production of preparations containing narcotic or psychotropic substances in Schedules III or IV, exempt chemical preparations, excluded products, or exempted prescription products may decide to recover the original bulk narcotic or psychotropic contained in the preparations for future use in other narcotic or psychotropic manufacturing procedures. Code "L" is the transaction code used to report this type of activity. The "L" transaction activity must be reported quarterly or annually for each ARCOS reportable narcotic or psychotropic substance recovered in schedules I and II. Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "L" transaction. Note, also, that for each unique NDC number, *transaction code L* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "L" Transaction Code:

From May 1 through August 30, 1997, a manufacturer's journal on chemical procedures cited the chemical recovery of 30 kgs of bulk raw dihydrocodeine bitartrate powder (NDC 00794-0111-**) and 5260 grams of bulk raw butalbital powder (NDC

00441-0525-**) from exempt prescription products. The following examples demonstrate the ARCOS reporting procedure.

6.4.3.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PG1234567	L		007940111**	00000030	4			123197	1000		0000000001	E25
PG1234567	L		004410525**	00005260	3			123197	1000		0000000002	E25

6.4.3.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	L		007940111**	000030	4				1000	71231	00001
PG1234567	L		004410525**	005260	3				1000	71231	00002

6.4.4 Sampling (Code Q)

A quality control feature associated with most manufacturing procedures involves the removal of a designated quantity of the manufactured product for stability testing (i.e. melting point, flashpoint, optical rotation, GLC-NMR spectra, etc.) or government sampling requirements. Any quantity of ARCOS reportable bulk or dosage form narcotic or specific psychotropic product (see selected list, 6.3.1) removed from inventory for sampling purposes is to be reported. Code "Q" is the transaction code used to reflect this type of activity. The "Q" transaction activity must be reported quarterly or annually for each ARCOS Reportable narcotic or psychotropic substance in Schedules I through IV.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "Q" transaction. Note, also, that for each unique NDC number, *transaction code Q* must be reported once at the end of each calendar quarter or annually on December 31.

6.4.5 Return of Samples to Inventory (Code J)

There are occasions when samples removed for quality control are returned to the manufacturing process. Code "J" is the transaction code used to reflect this type of activity. For each unique NDC number, report one *transaction code J* for the reporting period.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "J" transaction. Note, also, that for each unique NDC number, *transaction code J* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenarios for "Q" & "J" Transaction Codes:

The following example demonstrates the ARCOS reporting procedure for (a) removal of samples from inventory (Code Q) and (b) return of samples to inventory (Code J).

On May 22, 1997, a manufacturer withdrew a sample of 10 bottles of hydrocodone capsules

(NDC 00403-4522-30) for quality control testing; on November 10, 1997, the manufacturer returned 8 bottles of hyrdocodone bitartrate capsules (NDC 00403-4522-30) to inventory.

6.4.5.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PG1234567	Q		00403452230	00000010				123197			00000001	E25
PG1234567	J		00403452230	00000008				123197			00000002	E25

6.4.5.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	Q		00403452230	000010						71231	00001
PG1234567	J		00403452230	000008						71231	00002

NOTE: Exception to Usage Reporting

There is one instance in manufacturing where no reporting is needed:

When a quantity of a drug is used to produce an end product (such as a preparation) which contains the same drug in the same schedule, no reporting is necessary. For example, if a Schedule II drug is used to produce a Schedule II preparation containing that drug, it is not reported to ARCOS.

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PART III: SYSTEM OUTPUT

SECTION 7 EDIT LISTINGS

Version 1.0

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7

SECTION 7.0

EDIT LISTINGS

7.1 EDITING PROCESS

All ARCOS reports are initially subjected to two major procedures, the *control record* edit and the *transaction record* edit. These procedures check the reliability of the incoming data and determine whether and to what extent further processing will occur.

7.2 CONTROL RECORD EDIT

This initial procedure checks the *control record* submitted with each of the ARCOS reports. ARCOS reports that pass the validity tests performed on the *control record* continue on to the *transaction record* edit. An ARCOS report that fails the *control record* edit ***may*** be returned to the ARCOS registrant or central reporter for correction and resubmission. Returned reports are accompanied by a letter of explanation. Depending upon the nature and volume of the errors detected during the *control record* edit, the Data Systems Unit (ARCOS) may correct and resubmit a report ***after*** obtaining permission from the ARCOS registrant or central reporter.

7.3 TRANSACTION RECORD EDIT

The *transaction record* edit procedure examines all data fields in each incoming *transaction record* and rejects those records that do not meet pre-established criteria. This procedure produces the Daily Transaction Processing Error Report which is an error status report. The Daily Transaction Processing Error Report will either list all the *transaction records* with errors or contain a statement indicating that the current ARCOS report did not have any errors.

Receipt of the Daily Transaction Processing Error Report with no errors means that all the submitted *transaction records* were added to the ARCOS Master Transaction File. Exhibit 7.1: Accepted Report, illustrates the status report produced when no errors are detected.

When errors are detected, the Daily Transaction Processing Error Report lists each transaction record in error, the error code, a description of the error, and a correction number. These erroneous *transaction records* ***must*** be corrected and resubmitted with the next ARCOS report. Exhibit 7.2: Rejected Report, illustrates the report produced when *transaction records* fail the data reliability tests. Exhibits 7.1 and 7.2 are actual reports with the identifying data obliterated.

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DRUG ENFORCEMENT ADMINISTRATION
A R C O S 2
DAILY TRANSACTIONS PROCESSING
Caldwell Incorporation
222 Squirrell Lane
Boston, IB 22344

ERROR REPORT

ERRORS FOR CONTROL RECORD = = > PF9999999*033197M

THE ARCOS 2 TRANSACTION EDIT PROGRAM DID NOT FIND ANY ERRORS ON THE TRANSACTIONS SUBMITTED BY THE REPORTING REGISTRANT FOR THE CONTROL RECORD LISTED ABOVE.

Exhibit 7.1: Accepted Report

DATE: 04/26/97 DEPARTMENT OF JUSTICE PAGE: 1

DRUG ENFORCEMENT ADMINISTRATION
A R C O S 2
DAILY TRANSACTIONS PROCESSING
ERROR REPORT
Brown Incorporated
111 Howard Rd
Randolph, ST 11414

ERRORS FOR CONTROL RECORD = = > PB9999999*033197M

PB9999999 P 66157001860000000003AB12345670307970000273 2 0000000010
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
E48 ASSOCIATE REGISTRANT NUMBER ENTERED ISN'T A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00002732

PB9999999 P 66157001716000000002CD12345670307970000273 1 0000000011
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
E48 ASSOCIATE REGISTRANT NUMBER ENTERED ISN'T A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00002731

PB9999999 P 553014548670000013 2EF12345670306970000272 0 0000000012
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
CORRECTION NUMBER: 00002720

Exhibit 7.2: Rejected Report

7.4 TRANSACTION ERROR CODES

E01 Reporting Registrant Number Doesn't Match the One on the Control Record

Error Code E01 is issued when the Reporting Registrant's DEA registration number on the transaction record does not match the Reporting Registrant's DEA number on the control record.

E06 Delete Indicator Field Must Be Blank Or Must Be The Letters "A," "D," or "I"

The Action Indicator (formerly Delete Indicator) field must be blank or contain either an "A," "D," or "I." If it contains any other value, Error Code E06 is issued.

E07 Delete Indicator Field Must Be Blank If A Correction Number Is Present

Error Code E07 is issued when the Correction Number (formerly Lot Number) field is ***not*** blank and the Action Indicator (formerly Delete Indicator) field contains an "A," "D," or "I."

E12 Transaction Date Contains An Invalid Month And/Or An Invalid Day

Error Code E12 is issued when:

a. The Month is less than "01" or greater than "12"

b. The Day is less than "01" or greater than the maximum number of days in the month

c. The Year is not numeric

E13 Transaction Date Must Be The Last Day Of The Report Month Or Quarter

Error Code E13 refers to Transaction Code "7" ***only***. The Transaction Date field ***must*** be either the end of the month or the end of the quarter depending on the reporting frequency of the reporting registrant. Otherwise, Error Code E13 is issued.

E14 Transaction Code Requires A Year-End Date In The Transaction Date Field

Error Code E14 refers to inventory transaction codes "3," "8," and "4" ***only***. This error code is issued when the transaction date is not the last day of the year. The transaction date format is:

a. automated reporting: "1231**XX**" where "**XX**" is the year (last two-digits) in which the inventory was taken.

b. manual reporting: "**X**1231" where "**X**" is the year (last digit) in which the inventory was taken.

E15 Transaction Date Is Later Than The Run Date Of The ARCOS 2 Edit Program

The "run date" is the computer processing date. Error Code E15 is issued when the Transaction Date is the same or later than (i.e., in the future) the computer processing date. Transactions cannot be reported before they have occurred.

E16 Transaction Date Is Not Within The Reporting Registrants Report Period

Error Code E16 is issued when the Transaction Date is **before** or after the current reporting period ***and*** the transaction is ***not*** a correction, ***not*** a deletion, ***not*** an adjustment, ***and not*** a late transaction. The current reporting period is identified by the ending date and the reporting frequency ("M" or "Q") entered on the control record.

E17 Transaction Date Isn't Within The 2 Year Date Range Of The ARCOS System

The active ARCOS data base holds 24 months of data beginning with January 1, 1997. Transaction Records that have been in the active data base are archived after 24 months. Error Code E17 is issued when the transaction date is ***not*** within this range.

E21 Correction Number Entered Is Invalid. It Must Be Numeric

Error Code E21 is issued when the Error Correction Number field contains an invalid correction number or non-numeric data.

E22 Correction Number Is Not In The Error File

Error Code E22 is issued when the Error Correction Number on a Correction Transaction does ***not*** match a number in the Error file.

E25 The ARCOS Edit Still Found Errors On The Corrected Transaction

Error Code E25 is issued when a transaction flagged as a correction remains incorrect or contains a new error.

E28 Data Entered In The Quantity Field Is Invalid. It Must Be Numeric

Error Code E28 is issued when the Quantity field contains alphabetic or special characters. The Quantity field ***must only*** contain numeric data. This field is eight (8) digits in length for automated media and six (6) digits in length for manual media, including leading zeros. A zero quantity is invalid for all transaction codes, except for Transaction Code 5. The Quantity field is not checked for Transaction Codes F, 7, and 8.

E31 The Unit Value Entered Cannot Be Used With The Entered NDC Number

NDC identifies a finished dosage unit product:
Error Code E31 is issued when the Unit field is ***not*** blank, "D," or "K."

NDC identifies a raw bulk product (** package code):
Error Code E31 is issued when the Unit field is ***not*** a "1,""2," "3," "4," "5," or "6."

E32 Unit Value Must Be Blank, "D," "K," "1," "2," "3," "4," "5," or "6."

Error Code E32 is issued when the Unit field is ***not*** blank, "D," "K," "1," "2," "3," "4," "5", or "6."

E35 Strength Must Be Blank For Bulk Finished Or 0001 To 1000 For Bulk Raw

When the NDC identifies a ***finished bulk non-raw*** product:
The Strength field ***must*** be blank. Otherwise, Error Code E35 is issued.

When the NDC identifies a ***raw bulk*** product:
The Strength field ***must*** contain a value from "0001" to "1000". Otherwise, Error Code E35 is issued.

E36 Strength Is Invalid. Strength Must Be Blank Or Numeric

Error Code E36 is issued when the Strength field contains alphabetic or special characters. This field must be blank or contain a numeric value.

E40 Transaction Code Is Invalid. See The ARCOS Handbook For Valid Codes

The transaction code must be one of the following: "S," "P," "R," "Y," "T," "W," "M," "G," "Z," "N," "U," "V," "Q," "K," "J," "L," "X," "F," "1," "3," "4,, "5," "7,"or "8." Otherwise, Error Code E40 is issued.

E41 Transaction Code Is Reserved For Drug Manufacturers Only

Error Code E41 is issued when the reporting registrant is ***not*** a manufacturer, but reports a transaction using one of the following manufacturing transaction codes: "W," "M," "N," "U," "Q," "K," "J," "L," or "4."

E42 Transaction Code Requires Associate Registrant Number To Be Blank

Error Code E42 is issued when one of the following transaction codes is used: "T," "W," "M, "L," "N," "U," "Q," "J," "K," "F," "1," "3," "4," "5," "7," or "8" and the Associate Registration Number field (Field 7) is ***not*** blank.

E43 Associate Registrant Number Requires Transaction Code "Y," or "G," or "Z"

Error Code E43 is issued when the Associate Registrant Number field (Field 7) contains a DEA registration number for a DEA designated office or business and the transaction code is not Transaction Code Y, Transaction Code G, or Transaction Code Z.

E44 Transaction Code Conflicts With The NDC Number's CSA Schedule

Contact the Data Systems Unit (ARCOS) when Error Code 44 is issued. This error code applies to manufacturers ***only***. Certain drug schedules must be reported for certain manufacturing transaction codes.

E45 Transaction Code Requires An Associate Registrant Number Entry

Error Code E45 is issued when the transaction code is "S," "P," "R," "Y," "G," "Z," "V," or "X" ***and*** the Associate Registrant Number field (Field 7) does ***not*** contain a valid DEA registration number or one of the following entries, left justified: "RECALL," "OFFICER," "CIVILDEF," "UNKNOWN," "VESSELS," "NATIVE," or "MILITARY."

E46 Associate Registrant Number Is Invalid For Transaction Code "Y/G/Z"

Error Code E46 is issued when:

a. the firm holding the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** authorized to handle a ***Transaction Code Y*** activity (destruction of controlled substances) ***or***

b. the firm holding the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** authorized to handle a ***Transaction Code G or Z*** activity (controlled substances supplied or received by government).

E47 Associate Registrant Number Can't Equal Reporting Registrant Number

Error Code E47 is issued when the Associate Registrant Number (Field 7) is the same as the Reporting Registrant Number (Field 1). These two fields ***must not*** contain the same data.

E48 Associate Registrant Number Is Not A Valid DEA Registrant Number

Error Code E48 is issued when the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** found on DEA's master list of valid registration numbers.

E49 Associate Registrant Number Is Invalid For The Transaction Code

Error Code E49 is issued when the Associate Registrant Number field (Field 7) contains the entry "CIVILDEF," "RECALL," "OFFICER," "UNKNOWN, "VESSELS," "NATIVES," OR "MILITARY" and the corresponding transaction code entered in the Transaction Code field (Field 2) is incorrect. The correct pairing for the Associate Registrant Number field (Field 7) and the Transaction Code field is:

"CIVILDEF"	use	Transaction Codes	"S," "P," or "G"
"OFFICER"	use	Transaction Codes	"S," "P," "G," or "Z"
"RECALL"	use	Transaction Codes	"S" or "P"
"UNKNOWN"	use	Transaction Code	"V"
"VESSELS"	use	Transaction Codes	"S" or "P"
"NATIVE"	use	Transaction Codes	"S" or "P"
"MILITARY"	use	Transaction Codes	"S" or "P"

E52 The Order Form Number Has Not Been Correctly Entered

Error Code E52 is issued when an invalid Order Form Number has been entered in the DEA Order Form Number field (Field 8).

E53 The Order Form Number Is Required For Schedule 1 & 2 Drugs

Error Code E53 is issued when the Transaction Code is "S," "P," "R," "V," or "X", the NDC identified the product as a Schedule I or II controlled substance, ***and*** the Order Form Number field (Field 8) is blank.

E60 Transaction Code 1 -- An Inventory Record Already Exists

Error Code E60 is issued when a Schedule Change Inventory transaction record for the same NDC product already exists on the Master Transaction File.

E61 Transaction Code 3 or 8 -- Year-End Inventory Amount Already Exists

Error Code E61 is issued when:

a. A code 3 transaction record ***for the same NDC product*** has previously been added to the Master Transaction File or

b. A code 8 transaction record has previously been added to the Master Transaction File.

Delete the previously submitted transaction code 3 or transaction code 8 before resubmitting a different year end inventory amount.

E75 The NDC Number Is Invalid, It Contains One Or More Spaces

Error Code E75 is issued when the NDC is not in the format required by ARCOS or no NDC has been entered.

E76 The NDC Number Is Not In The Drug File

Error Code E76 is issued when the NDC can't be found in the ARCOS Master Drug file. To add a product to the ARCOS Master Drug File, manufactures, repackers, and relabelers must provide the Data Systems Unit (ARCOS) with the product's label, a copy of the label, or the completed FDA Drug Product Listing form (FDA-2657).

E77 NDC Number Isn't ARCOS Reportable. Don't Submit Corrected Transaction

Error Code E77 is issued when the product described by the NDC is ***not*** reportable to ARCOS. Do ***not*** re-submit any transactions for this product.

7.5 CORRECTING TRANSACTION RECORDS

Error processing for both ARCOS registrants and DEA has been simplified and streamlined. For registrants submitting ARCOS reports on magnetic media (automated), corrections, deletions, adjustments, and late transactions can be submitted ***along with*** the next monthly or quarterly report. There is no longer any need for errata media. Transactions for corrections, deletions, adjustments, and late items are placed ***after*** the last transaction in the current report. See Section 4, Control Record, for examples.

ARCOS registrants reporting on manual media (DEA Form 333), also submit corrections, deletions, adjustments, or late transactions ***along with*** the next monthly or quarterly report. As with reporting on magnetic media, reporters using the DEA Form 333 must keep the *control record* and its associated transactions together. Corrections, deletions, adjustments, and late transactions are coded on the DEA Form 333 ***after*** the last transaction of the current report. See Section 4, Control Record, for examples.

7.5.1 Error Categories

The following four types of transactions are used to correct errors and omissions in previously submitted ARCOS:

- **Correction Transaction**

  A Correction Transaction ***corrects*** a *transaction record* that has been rejected by the ARCOS editing programs. This transaction is submitted ***only after*** the original transaction has been listed on the Daily Transaction Processing Error Report as a rejected transaction..

- **Delete Transaction**

  The Delete Transaction ***removes*** a *transaction record* from the Master Transaction File. A Delete Transaction is submitted when the existing *transaction record* will ***not*** be replaced.

- **Adjustment Transaction**

  An Adjustment Transaction is used when the ARCOS editing programs have not rejected an original transaction, but the transaction is found by the submitting registrant to be inaccurate. In these instances, the Daily Transaction Processing Error Report will not list the *transaction record*. The Adjustment Transaction replaces the originally inaccurate *transaction record* in the Master Transaction File.

- **Late Transaction**

  A *transaction record* that was ***omitted*** from a ***prior*** report is ***submitted*** with the ***current*** report using the Late Transaction.

7.6 CORRECTION TRANSACTION

A Correction Transaction ***corrects*** a transaction that has been rejected by the data validation procedures. Rejected *transaction records* are listed in the Daily Transaction Processing Error Report and have been added to the *ARCOS transaction error file*.

7.6.1 Error Report

The Daily Transaction Processing Error Report will be mailed to each reporter after the transactions have been through the data validation procedures. The error report includes the following information:

a. Each transaction that contains one or more errors.

b. An error code and its meaning for each error.

c. A *correction number* for each erroneous transaction.

The *Correction Number* can be found on the error report, listed ***under*** the errors for each transaction and labeled "Correction No." Exhibit 7.3: Sample Error Transactions are transactions as they appear on the error report. However, for these examples, the ***errors*** and the ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

ERRONEOUS TRANSACTIONS

PA9999999S 0054375144000000002 **B9**9900099**PO**2463899070694 0000000102E25
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000022**
^^^^^^^^

PA9999999S 0054375144000000002 B99900099**P0**2463899**13**0694 0000000102E25
^^ ^^

E12 THE TRANSACTION DATE CONTAINS EITHER AN INVALID MONTH OR AN INVALID DAY

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000023**
^^^^^^^^

Exhibit 7.3: Sample Error Transactions

7.6.2 Correction Process

A Correction Transaction ***must be*** submitted for each erroneous transaction to be corrected. To correct a rejected record, submit a correction transaction with the ***next quarterly*** or ***monthly*** report. Correction Transactions ***may be placed after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.6.3 Correction Record

The *correction transaction record* has two formats, one for automated reporting and one for manual reporting. They are the ***same*** formats as the ARCOS *transaction record* formats with one exception - - the addition of the *correction number*. The *correction transaction record* ***must*** contain:

a. ***all*** the fields that were correct on the original submission ***including*** the original transaction identifier

b. the corrected fields

c. the *correction number*

7.6.4 Correction Number

A *correction number* is assigned to each erroneous transaction during the data validation process. This number is a unique, 8-digit, sequential number. There is ***only one*** *correction number* per erroneous transaction, even when a transaction has multiple errors.

7.6.4.1 Correction Number Format

The format for the *correction number* is: NNNNNNNN. Examples of this unique, sequential number are: 00000422, 00000423, and 00000424.

7.6.4.2 Correction Number Position

The *correction number* occupies the space formerly identified as the "Lot Number" field on the *transaction record*, Field 10 (automated media) and Field 9 (Manual Media, DEA Form 333). The field positions are:

a. positions 56 - 63 (automated media)

or

b. positions 48 - 55 (manual media, DEA Form 333)

7.6.5 Correction Transaction Examples

7.6.5.1 Automated Media

The following transaction would appear on the error report sent from DEA (ARCOS). *For this example*, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S 0054375144500000002 **B9**9900099**PB**2463899070697 0000000102E25
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN **CORRECTLY** ENTERED ON THE TRANSACTION

CORRECTION NO. **00000422**
^^^^^^^^

These errors ***must*** be corrected by including the following correction transaction in the ***next*** monthly or quarterly ARCOS report. *For this example*, the ***corrections*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S 0054375144500000002 **BB**9900099**PB**2463899070697**00000422** 0000000102E25
^^ ^^ ^^^^^^^^

7.6.5.2 Manual Media

The following transaction would appear on the error report sent from DEA (ARCOS). *For this example*, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol. underneath with the "^" symbol.

PA9999999S 00543751444000002 **AB**9900099**PB**2463899 7022800102
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000422**
^^^^^^^^

These errors ***must*** be corrected by including the following correction transaction in the ***next*** monthly or quarterly ARCOS report. For this example, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

```
PA9999999S 00543751444000002 AA9900099PB246389900000422   7022800102
                             ^^         ^^         ^^^^^^^^
```

7.7 DELETION TRANSACTION

7.7.1 Delete Process

The Deletion Transaction ***removes*** a *transaction record* from the Master Transaction File. A *deletion record* is submitted when the ***existing*** *transaction record* will ***not*** be replaced. To remove an existing record from the Master Transaction File submit a *deletion record* with the ***next*** monthly or quarterly report. *Deletion records* ***may be placed after*** the *transaction records* for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's.

7.7.2 Deletion Record

The *deletion record* is a ***duplicate*** of the original *transaction record* plus the *delete indicator*. The *deletion record* ***must*** contain:

a. ***all*** the fields that were in the original *transaction record*, ***including*** the original *transaction identifier* number.

b. "D" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.7.3 Deletion Examples

An ARCOS registrant wants to remove the following *transaction record* from the data base. Examples of both automated and manual reporting are provided. The *action indicator* "D" (delete), appears in **bold-faced** type and marked underneath with the "^" symbol.

Original Transaction Record: automated media

```
PA9999999S 0054375144700000008 AB990009940246389907039 7          0000000102E25
```

Deletion Record: automated media

```
PA9999999SD0054375144700000008 AB990009940246389907039 7          0000000102E25
           ^
```

Original Transaction Record: manual media

```
PA9999999S 00543751444000002 AB9900099PB2463899          7022800102
```

Deletion Record: manual media

```
PA9999999SD00543751444000002 AB9900099PB2463899          7022800102
           ^
```

7.8 ADJUSTMENT TRANSACTION

DEA (ARCOS) recognizes two types of *transaction record* flaws in ARCOS data: mistakes and errors. Errors are data flaws caught by the ARCOS programs during the data validation process. *Transaction record*s containing errors are added to the Error Transaction File. These records must be corrected and resubmitted.

Mistakes are data flaws ***not*** caught by the ARCOS programs but discovered by the submitting ARCOS registrant. *Transaction records* containing mistakes ***are added*** to the Master Transaction File, since these records have met all the processing criteria. For example, the submitting ARCOS registrant enters "20" in the *quantity* field. This entry passes the data validity tests and the *transaction record* is added to the data base. However, the reporting registrant had originally ***intended*** to enter "200", but had mistakenly entered "20 ". That mistake would ***not*** be caught by the data validity tests. This *transaction record* with the ***incorrect, but valid*** data would be added to the Master Transaction File. This mistake must be ***rectified*** by using the adjustment transaction. An adjustment transaction ***revises*** a *transaction record* that has been added to the Master Transaction File.

7.8.1 Adjustment Process

The Adjustment Transaction corrects an existing ARCOS Master Transaction File record by replacing it. When an ARCOS registrant discovers a mistake in a previously submitted transaction, the registrant ***must wait until*** the Daily Transaction Processing Error Report is

received from DEA (ARCOS) ***before*** taking any action. Whether or not the transaction is listed in the error report determines whether an Adjustment Transaction or a Correction Transaction must be submitted.

A transaction containing mistakes that can ***only*** be identified by the ARCOS registrant is ***not*** listed in the Error Report. In this case an ***Adjustment Transaction must*** be submitted to correct the mistake. A transaction containing ***both errors and mistakes*** is rejected and listed in the error report. However, only the errors are specifically identified and listed in the error report. Mistakes ***are not*** caught by the ARCOS programs, and therefore, are not specifically listed in the error report. A ***Correction Transaction must*** be used to correct this *transaction record*. See Section 7.6, Correction Transaction. Both the Adjustment Transaction or Correction Transaction ***must*** be submitted with the ***next*** monthly or quarterly ARCOS report ***after*** the error or mistake has been discovered. These transactions ***may be placed after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.8.2 Adjustment Records

An Adjustment Transaction consists of ***two*** records, the *deletion record* and the *adjustment record*

7.8.2.1 Deletion Record

The *deletion record* is the ***first*** record of the two records. It is a ***duplicate*** of the original *transaction record* plus the *action indicator*. The *deletion record* ***must*** contain:

a. ***all*** the fields that were in the original *transaction record*, ***including*** the original *transaction identifier* number.

b. "D" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.8.2.2 Adjustment Record

The ***second*** record of the two records, the *adjustment record*, is the ***revised*** *transaction record*. The *adjustment record* ***must*** contain:

a. ***all*** the fields that ***were correct*** in the original transaction ***including*** the original *transaction identifier* number.

b. ***all*** the ***corrected*** fields.

c. "A" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.8.3 Adjustment Transaction Examples

7.8.3.1 Automated Media: Incorrect Quantity

In the original transaction the *quantity* field was mistakenly coded as "00000002." However, since this quantity met the editing criteria, the transaction was accepted and added to the Master Transaction File. This *transaction record* ***does not*** appear on the error report, but the original entry was incorrect and must be changed to the correct amount, "00000020"(i.e., from "2" to "20").

Original Transaction

The following transaction, originally reported to DEA (ARCOS), ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *quantity* field appears in **bold-faced** type and underneath with the "^" symbol.

```
PA9999999S 0054375144000000002 AB990009940246389907039 4          0000000102E25
                                ^^
```

Adjustment Pair

The following adjustment pair was submitted to correct the *quantity* field. *For this example,* the *quantity* field and the *action indicator* (formerly *delete indicator*) field appear in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record

PA9999999S**D**00543751440000000**02** AB990009940246389907039400000000102E25
^ ^^

Adjustment Record

PA9999999S**A**00543751440000000**20** AB990009940246389907039400000000102E25
^ ^^

7.8.3.2 Automated Media: Wrong Transaction Code

This next adjustment example changes an incorrect *transaction code*. A "sales" *transaction record* was mistakenly submitted. Originally, the *transaction record* should have been submitted as a "purchase" transaction.

Original Transaction

The following transaction, originally reported to ARCOS, does ***not*** appear in the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *transaction code* field is in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999**S** 00543751440000000012 AB990009940246389907199400000000199E25
^

Adjustment Pair

The following adjustment pair was submitted to correct the mistake in the *transaction code* field. *For this example*, the *transaction code* field and the *action indicator* (formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record

PA9999999**SD**0054375144000000012 AB990009940246389907199 4 0000000199E25
^^

Adjustment Record

PA9999999**PA**0054375144000000012 AB990009940246389907199 4 0000000199E25
^^

7.8.3.3 Manual Media: Incorrect Quantity

In the original transaction the *quantity* field was mistakenly coded as "000005." Nevertheless, this quantity met the editing c riteria, the *transaction record* was accepted, and added to the data base. This transaction ***does not*** appear on the error report, but since the original entry was incorrect, it ***must*** be changed to the correct amount "000050" (i.e., from "5" to "50").

Original Transaction

The following transaction, originally reported to ARCOS, ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *quantity* field is in **bold-faced** type and marked underneath with the "**^**" symbol.

PA9999999S 00543751440000**05** AB9900099402463899 4070300102
^^

Adjustment Pair

The following adjustment pair was submitted to correct the *quantity* field. *For this example,* the *action indicator* (formerly *Delete Indicator)* field and the *quantity* field are in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record

PA9999999S**D**00543751440000**05** AB9900099402463899 4070300102
^ ^^

Adjustment Record

PA9999999S**A**00543751440000**50** AB9900099402463899 4070300102
^ ^^

7.8.3.4 Manual Media: Wrong Transaction Code

The next adjustment example changes an incorrect *transaction code*. A "sales" *transaction record* was mistakenly submitted. Originally, the *transaction record* should have been submitted as a "purchase" transaction.

Original Transaction

The following transaction, originally reported to DEA (ARCOS), ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *transaction code* is in **bold-faced** type and marked underneath with the "^" symbol.

```
PA9999999S 00543751440000012 AB9900099402463899          4071900199
           ^
```

Adjustment Pair

The following adjustment pair was submitted to correct the *transaction code* field. For this example, the *transaction code* field and the *action indicator* (formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record

```
PA9999999SD00543751440000012 AB9900099402463899          4071900199
           ^^
```

Adjustment Record

```
PA9999999PA00543751440000012 AB9900099402463899          4071900199
           ^^
```

7.9 LATE TRANSACTION

The Late Transaction enables a *transaction record* omitted from a prior ARCOS report to be accepted with the current ARCOS report.

7.9.1 Reporting Period and Frequency

ARCOS registrants must report their controlled substance transactions to DEA (ARCOS) on a monthly or a quarterly basis. Each ARCOS report, ***except*** for transactions that adjust, delete, or correct previously submitted transactions, ***must only*** contain controlled substance transactions that are within the period being reported. A monthly reporter with a reporting period ending date of February 28, 1997 (022897) on the *control record*, must have *transaction records* with dates that are from February 1, 1997 through February 28, 1997 (except for corrections, deletions, adjustments, and late transactions). A quarterly reporter with a reporting period ending date of June 30, 1997 (063097) on the *control record*, must have *transaction records* with dates that are from April 1, 1997 through June 30, 1997 (except for corrections, deletions, adjustments, and late transactions).

7.9.2 Reporting Period Test

ARCOS processing checks the *transaction date* of each *transaction record* to determine if it is within the ARCOS registrant's current reporting period. Each transaction that falls outside of the current reporting period ***and*** is ***not*** identified as a late, correction, adjustment, or deletion transaction is rejected as erroneous. These transactions appear on the Daily Transaction Processing Error Report with an error message indicating that the *transaction date* is not within the current reporting period.

Example 1:

An ARCOS registrant with a monthly reporting frequency includes *transaction records* with February *transaction dates* in its March ARCOS report. These *transaction records* are neither adjustments nor corrections to previously submitted transactions; they are being reported for the first time. Since the *transaction dates* reported lie outside the current reporting period, March, the *transaction records* are rejected and listed on the Daily Transaction Processing Error Report.

Example 2:

An ARCOS registrant with a quarterly reporting frequency includes *transaction records* with second quarter (April, May, June) *transaction dates* in its third quarter (July, August, September) ARCOS report. These *transaction records* are neither adjustments nor corrections to previously submitted transactions; they are being reported for the first time. Since the *transaction dates* reported lie outside the current reporting period, the third quarter of the year, the *transaction records* are rejected and listed on the Daily Transaction Processing Error Report.

7.9.3 Submission and Acceptance

A Late Transaction is submitted as an Insertion Record. This record has an "***I***" coded in the *action indicator* (formerly *Delete Indicator*) field (Field 3). A Late Transaction that is missing the insertion code, "I," in the *action indicator* field, will be rejected with an E16, *transaction date* Is Not Within the Reporting Registrants Report Period" error code. ***Late Transactions*** are included in an ARCOS Registrant's current report. They may be placed ***after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.9.4 Late Transaction Examples

7.9.4.1 Automated Media: Late Transaction

A January transaction was inadvertently omitted from a monthly reporter's January 1997 report. Subsequently, the transaction was submitted in the reporter's March 1997 report. To have this transaction pass the pass the *transaction date* test, an "***I***" ***must*** be entered in the *action indicator* (formerly *Delete Indicator*) field (Field 3, position 11). The transaction below illustrates the correct coding when a late transaction is ***initially*** submitted. For this example, the *transaction date* field and the *action indicator (*formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

```
PA9999999SI00543751440000000020 AB990009940246389901069 7          0000000102E25
           ^                                    ^^^^^^
```

7.9.4.2 Manual Media: Late Transaction

An April transaction was inadvertently omitted from a monthly reporter's April 1997 report. Subsequently, the transaction was submitted in the reporter's July 1997 report. To have this transaction pass the pass the *transaction date* test, an ***"I" must*** be entered in the *action indicator* (formerly *delete indicator*) field (Field 3, position 11). The transaction below illustrates the correct coding when a late transaction is ***initially*** submitted. For this example, the *transaction date* field and the *action indicator (*formerly *delete indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

```
PA9999999SI00543751440000020 AB9900099402463899      7040600102
           ^                                         ^^^^^
```

7.9.5 TRANSACTION IDENTIFIER

The *transaction identifier* for a late transaction is the next, sequential number in the ARCOS report for the reporting period in which the late transaction should have occurred. For example, an ARCOS registrant is submitting three late transactions with its current quarterly report for the quarter ending June 30, 1997. One late *transaction record* has a *transaction date* occurring in January, and the other two have *transaction dates* occurring in March. These three transactions were omitted from the ARCOS report for the first quarter of 1997. The *transaction identifiers* for these three late transactions will be the next three sequential numbers that ***would have occurred*** in the ARCOS report for the first quarter of 1997.

APPENDIX 1

ARCOS TRANSACTION MATRIX: AUTOMATED REPORTS

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
INVENTORY TRANSACTIONS													
Sched. Chng.	B	1		B	B	O			B	O	O	B	B
Year-end	B	3		B	B	O			B	O	O	B	B
In-Process	B	4		B	B	O			B	O	O	B	B
Special	B	5		B	B	O			B	O	O	B	B
No Year-end	B	8							B	O		B	B
ACQUISITION TRANSACTIONS													
Purchase or Other Receipt	B	P		B	B	O	ASSOC REG # OR RECALL B, C	H	B	O	O	B	B
Return	B	R		B	B	O	ORIG. ASSOC REGIS. # B, C	ORIG. DEA ORD. FORM H	B	O	O	B	B
Recovered Waste	B	W		B	B	O			B	O	O	B	B
Manufactured	B	M		B	B	O			B	O	O	B	B
Reversing	B	L		B	B	O			B	O	O	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Version 1.0 August 1997

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
Government Supplied	B	G		B	B	O	DEA/FDA #, OFFICER, OR CIVIL DEF B		B	O	O	B	B
Ret. Sample to Inventory	B	J		B	B	O			B	O	O	B	B
Unsol. Return	B	V		B	B	O	B, *	H	B	O	O	B	B
DISPOSITION TRANSACTIONS													
Sale, Disposition, or Transfer	B	S		B	B	O	ASSOC REGIS #, RECALL B, C	H	B	O	O	B	B
Destroyed	B	Y		B	B	O	DEA REGIONAL # B		B	O	O	B	B
Theft	B	T		B	B	O			B	O	O	B	B
Non-recov. Waste	B	N		B	B	O			B	O	O	B	B
Used in Prod.	B	U		B	B	O			B	O	O	B	B
Used in Prep.	B	K		B	B	O			B	O	O	B	B

B Mandatory.
C Normally: Associate Registration Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSEL, NATIVE, MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

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Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
Receipt by Government or Seizure	B	Z		B	B	O	DEA/FDA #, OFFICER B		B	O	O	B	B
Sampling	B	Q		B	B	O			B	O	O	B	B
DELETION, ADJUSTMENT, AND LATE TRANSACTIONS													
Deletion	B	B	D	Fields 2 and 4-13: Enter the same information as was entered on the original transaction.									
Adjustment	B	B	A	Fields 4-13: Enter the original information for unchanged fields and the revised information for changed fields.									
Late	B	B	I	Fields 4-13: Enter normal transaction information.									
MISCELLANEOUS TRANSACTIONS													
No Period Act	B	7							B			B	B
Lost-in-Transit	B	X		B	B	O	B	H	B		O	B	B
Order DEA Form 333	B	F			O				B			B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

APPENDIX 2
ARCOS TRANSACTION MATRIX: MANUAL REPORTS

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Trans. ID (14)
INVENTORY TRANSACTIONS														
Sch. Chg	B	1		B	B	O			O	O	B	B	B	B
Year-end	B	3		B	B	O			O	O	B	B	B	B
In-Proc	B	4		B	B	O			O	O	B	B	B	B
Special	B	5		B	B	O			O	O	B	B	B	B
No Yr end	B	8							O		B	B	B	B
ACQUISITION TRANSACTIONS														
Purchase or Other Receipt	B	P		B	B	O	ASSOC REG # OR RECALL B, C	H	O	O	B	B	B	B
Return	B	R		B	B	O	ORIGINAL ASSOC REG NUMBER B, C	ORIGINAL ORDER FORM NUMBER H	O	O	B	B	B	B
Recov. Waste	B	W		B	B	O			O	O	B	B	B	B
Manufac.	B	M		B	B	O			O	O	B	B	B	B
Reversing	B	L		B	B	O			O	O	B	B	B	B

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* Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Tranced (14)
Govern-ment Supplied	B	G		B	B	O	DEA/FDA # OFFICER CIVILDEF B		O	O	B	B	B	B
Return Sample to Inventory	B	J		B	B	O			O	O	B	B	B	B
Unsol. Return	B	V		B	B	O	B, *	H	O	O	B	B	B	B
DISPOSITION TRANSACTIONS														
Sale, Disposition, or Transfer	B	S		B	B	O	ASSOC REG # CIVILDEF OFFICER RECALL B	H	O	O	B	B	B	B
Destroyed	B	Y		B	B	O	DEA REGIONAL REG # B		O	O	B	B	B	B
Theft	B	T		B	B	O			O	O	B	B	B	B
Non-recov. Waste	B	N		B	B	O			O	O	B	B	B	B
Used in Production	B	U		B	B	O			O	O	B	B	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY.
* Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Tranced (14)
Used in Preparation	B	K		B	B	O			O	O	B	B	B	B
Receipt by Government or Seizure	B	Z		B	B	O	DEA/FDA #, Officer B		O	O	B	B	B	B
Sampling	B	Q		B	B	O			O	O	B	B	B	B
DELETION, ADJUSTMENT, AND LATE TRANSACTIONS														
Deletion	B	B	D	Fields 2 and 4-14: Enter the same information as was entered on the original transaction.										
Adjustment	B	B	A	Fields 4-14: Enter the original information for unchanged fields and the revised information for changed fields.										
Late	B	B	I	Fields 4-14: Enter normal transaction information.										
MISCELLANEOUS TRANSACTIONS														
No Activity	B	7							O		B	B	B	B
Lost-in-Transit	B	X		B	B	O	B	H	O	O	B	B	B	B
Order DEA Form 333	B	F			O				O		B	B	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY.
* Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

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APPENDIX 3

CONVERSION FACTORS FOR CONTROLLED SUBSTANCES (FROM SALT TO ANHYDROUS BASE OR ACID)

11-HYDROXY DELTA-9 TETRAHYDROCANNABINOL	0.9595
2,5-DIMETHOXYAMPHETAMINE HCL(2,5-DMA)	0.8427
(-)2 -CARBOMETHOXY-3 -(4-FLUOROPHENYL)TROPANE	0.3275
3,4-METHYLENEDIOXYAMPHET ACETATE	0.7491
3,4-METHYLENEDIOXYAMPHET HCL	0.8310
3,4-METHYLENEDIOXYAMPHET S04	0.6463
4-ETHYL-2,5-DIMETHOXYAMPHET HCL(DOET.HCL)	0.8598
4-METHOXYAMPHETAMINE HCL(PMA)	0.8190
4-METHYL-2,5-DIMETHOXYAMPHET HCL(STP OR DOM)	0.8586
ALFENTANIL HYDROCHLORIDE	0.9280
ALPHA-ETHYL TRYPTAMINE ACETATE	0.7584
ALPHAMETHADOL HYDROCHLORIDE	0.8952
ALPHANORMETHADOL HCL	0.8952
ALPHAPRODINE HYDROCHLORIDE	0.8776
ALPHENAL SODIUM	0.9174
AMINOPROPYLMORPHINE	0.8333
AMOBARBITAL SODIUM	0.9114
AMPHETAMINE HYDROIODIDE	0.5515
ANILERIDINE DIHYDROCHLORIDE	0.8286
ANILERIDINE PHOSPHATE	0.7825
APROBARBITAL SODIUM	0.9052
BARBITAL SODIUM	0.8933
BENZPHETAMINE HYDROCHLORIDE	0.8678
BETAPRODINE MALATE	0.6609
BUFOTENINE MONOOXOLATE.H20	0.6538
BUPRENORPHINE HYDROCHLORIDE	0.9275
BUTABARBITAL SODIUM	0.9062
BUTALBITAL SODIUM	0.8549
BUTALLYLONAL SODIUM	0.9295
CANNABINOL ACETATE	0.8807
CATHINONE HCL	0.8036
CHLORAL BETAINE	0.5216
CHLORAL HYDRATE	0.8911
CHLORDIAZEPOXIDE HYDROCHLORIDE	0.8916
CHLORPHENTERMINE.HCL	0.8344
CLORAZEPATE DIPOTASSIUM	0.8137
CLORAZEPATE MONOPOTASSIUM	0.8924
CLORTERMINE.HCL	0.8344
COCAINE HYDROCHLORIDE	0.8927
COCAINE NITRATE	0.8280
COCAINE AMINO	0.9528
COCAINE-D3(DEUTERATED)	0.9903
CODEINE ACETATE	0.8329
CODEINE HYDROCHLORIDE	0.8914

CODEINE METHYLBROMIDE	0.7592
CODEINE PHOSPHATE.1/2H20	0.7367
CODEINE SULFATE.3H20	0.7974
CODEINE-6-GLUCURONIDE	0.6296
CODEINE-D3(DEUTERATED)	0.9900
CODEINE-N-OXIDE	0.9493
CYCLOBARBITAL CALCIUM	0.9255
CYPRENORPHINE HYDROCHLORIDE	0.9207
D-AMPHETAMINE ADIPATE	0.4807
D-AMPHETAMINE CARBOXYMETHYLCELLULOSE SALT	0.2593
D-AMPHETAMINE HYDROCHLORIDE	0.7876
D-AMPHETAMINE P04,DIBASIC	0.7340
D-AMPHETAMINE P04,MONOBASIC	0.5798
D-AMPHETAMINE SACCHARATE	0.3915
D-AMPHETAMINE S04.DIBASIC	0.7338
D-AMPHETAMINE SULFATE MONOBASIC	0.5796
D-AMPHETAMINE TANNATE	0.2956
D-EPHEDRINE HCL	0.8192
D-METHAMPHETAMINE HI	0.5385
D-METHAMPHETAMINE HYDROBROMIDE	0.6688
D-METHAMPHETAMINE HYDROCHLORIDE	0.8037
D-METHAMPHETAMINE SACCHARATE	0.4153
D-METHAMPHETAMINE SULFATE	0.7527
D-PSEUDOEPHEDRINE HCL	0.8192
DESOMORPHINE HYDROCHLORIDE	0.8816
DEXTROMORAMIDE BITARTRATE	0.7233
DEXTROMORAMIDE HYDROCHLORIDE	0.9150
DEXTROPROPOXYPHENE HYDROCHLORIDE	0.9030
DEXTROPROPOXYPHENE NAPSYLATE	0.6001
DIETHYLPROPION HYDROCHLORIDE	0.8492
DIETHYLTRYPTAMINE HYDROCHLORIDE	0.8556
DIFENOXIN HYDROCHLORIDE	0.9208
DIHYDROCODEINE BITARTRATE	0.6675
DIHYDROHYDROXYCODEINONE HYDROCHLORIDE	0.8964
DIHYDROMORPHINONE SULFATE	0.8533
DIMETHYLTRYPTAMINE FUMURATE	0.6230
DIPHENOXYLATE HYDROCHLORIDE	0.9254
DIPRENORPHINE HYDROCHLORIDE	0.9051
DIPROPYLTRYPTAMINE HYDROCHLORIDE	0.8720
DL-2-METHOXY-4,5-METHYLENEDIOXYAMPHETAMINE HCL	0.8518
DL-AMPHETAMINE ADIPATE	0.4806
DL-AMPHETAMINE ASPARTATE	0.5039
DL-AMPHETAMINE HYDROCHLORIDE	0.7876
DL-AMPHETAMINE P04,DIBASIC	0.7340
DL-AMPHETAMINE P04,MONOBASIC	0.5798
DL-AMPHETAMINE POSTASSIUM SACCHARATE	0.3526
DL-AMPHETAMINE SULFATE DIBASIC	0.7338
DL-AMPHETAMINE SULFATE MONOBASIC	0.5796
DL-AMPHETAMINE TANNATE	0.2956

DL-AMPHETAMINE-D11(DEUTERATED)	0.9243
DL-AMPHETAMINE-D6(DEUTERATERD)	0.9572
DL-EPHEDRINE HCL	0.8192
DL-METHAMPHETAMINE HI	0.5385
DL-METHAMPHETAMINE HYDROCHLORIDE	0.8037
DL-METHAMPHETAMINE-D9(DEUTERATED)	0.9428
DL-METHAMPHETAMINE-D9(DEUTERATED)	0.9428
DL-PSEUDOEPHEDRINE HCL	0.8192
ECGONINE BENZOATE-D3 (DEUTERATED)	0.6336
ECGONINE BENZOATE-D3-.4H20	0.5083
ECGONINE BENZOYLPROPYLESTER	0.5589
ECGONINE BENZOYLPROPYLESTER HCL	0.5035
ECOGONINE BENZOATE, ANHYDROUS	0.6402
ETHYLMORPHINE HYDROCHLORIDE	0.8121
ETHYLMORPHINE METHYLIODIDE	0.6883
ETICYCLIDINE HYDROCHLDRIDE(ETHYLAMINE ANOLOG)	0.8480
ETONITAZENE HYDROCHLORIDE	0.9158
ETORPHINE HCL	0.9186
FENCAMFAMIN HYDROCHLORIDE	0.8552
FENFLURAMINE HYDROCHLORIDE	0.8638
FENTANYL CITRATE	0.6365
FENTANYL HYDROCHLORIDE	0.9022
FLURAZEPAM HYDROCHLORIDE	0.8418
HEROIN HYDROCHLORIDE BROWN	0.9102
HEROIN HYDROCHLORIDE WHITE	0.9102
HEXETHAL SODIUM	0.9161
HEXOBARBITAL SODIUM	0.9148
HYDROCODONS BITARTRATE	0.6054
HYDROCODONE TEREPHTHALATE	0.6431
HYDROCODONE-D3(DEUTERATED)	0.9900
HYDROCODONE-D6(DEUTERATED)	0.9802
HYDROMORPHINOL BITARTRATE	0.6435
HYDROMORPHONE HYDROCHLORIDE	0.8867
HYDROMORPHONE-D3(DEUTERATED)	0.9895
IBOGAINE HYDROCHLORIDE	0.8948
KETAMINE HYDROCHLORIDE	0.8670
L-EPHEDRINE HCL	0.8192
L-PSEUDOEPHEDRINE HCL	0.8192
LEVALPHAACETYLMETHADOL.HCL(LAAM.HCL)	0.9065
LEVAMPHETAMINE MUCATE	0.5338
LEVAMPHETAMINE P-AMINOBENZOATE	0.5254
LEVAMPHETAMINE S04 DIBASIC	0.7338
LEVAMPHETANINE SUCCINATE	0.5337
LEVMETHAMPHETAMINE HYDROCHLODIDE	0.8037
LEVORPHANOL HBR	0.7608
LEVORPHANOL HCL	0.8759
LEVORPHANOL TARTRATE	0.5803
LYSIGERIDE TARTRATE(D-LSD TART.)	0.8117
MBDB.HCL (N-CH3-1-(3,4-METHYLENEDIOXYPHENYL) -2-BUTANAMINE.HCL)	0.8505
MDE.HCL	

(N-ETHYL-3,4-METHYLENEDIOXYAMPHETAMINE.HCL)	0.8504
MECLOQUALONE HYDROCHLORIDE	0.8813
MEFENOREX HYDROCHLORIDE	0.8531
MEPERIDINE HCL	0.8715
MEPERIDINE INTERMEDIATE B HYDROBROMIDE	0.7535
MEPERIDINE-D4(DEUTERATED)	0.9838
MEPHOBARBITAL SODIUM	0.9146
MESCALINE ACID SULFATE	0.6829
MESCALINE HYDROCHLORIDE	0.8528
MESCALINE SULFATE	0.3922
META-OH BENZOYL ECGONINE	0.6066
METHADONE HYDROBROMIDE	0.7922
METHADONE HYDROCHLORIDE	0.8946
METHAQUALONE HYDROCHLORIDE	0.8729
METHAQUALONE-D7(DEUTERATED)	0.9726
METHARBITAL SODIUM	0.9002
METHCATHINONE HCL	0.8174
METHOHEXITAL SODIUM	0.9226
METHYLPHENIDATE HYDROCHLORIDE	0.8648
METHYLPHENIDATE-D3(DEUTERATED)	0.9872
METHYLPHENIDATE-D3-HCL(DEUTERATED SALT)	0.8552
METOPON HYDROCHLORIDE	0.8914
MIDAZOLAM HCL	0.8969
MORPHINE ACETATE	0.7144
MORPHINE HYDROBROMIDE	0.7790
MORPHINE HYDROCHLORIDE	0.8866
MORPHINE NITRATE	0.8191
MORPHINE PHOSPHATE,MONO	0.7444
MORPHINE SULFATE PENTAHYDRATE	0.7521
MORPHINE, MONOHYDRATE	0.9405
MORPHINE-3-ETHEREAL SULFATE	0.7809
MORPHINE-3-GLUCURONIDE	0.6183
MORPHINE-3-GLUCURONIDE(D3)	0.6143
MORPHINE-D3(DEUTERATED)	0.9895
N-OH-3,4 METHYLENEDIOXYAMPHET HCL	0.8426
NALBUPHINE HCL	0.9074
NALMEFENE HYDROCHLORIDE	0.9030
NALORPHINE HYDROCHLORIDE	0.8952
NALTREXONE HYDROCHLORIDE	0.9035
NORACYMETHADOL HYDROCHLORIDE	0.9030
NORCODEINE HYDROCHLORIDE	0.7592
NOREGONINE	1.0820
NORMORPHINE HYDROCHLORIDE	0.8328
NOROXYMORPHONE HYDROCHLORIDE	0.8808
OXYCODONE HYDROCHLORIDE	0.8964
OXYCODONE TEREPHTRALATE	0.7915

OXYMORPHONE HCL,MONOHYDRATE	0.8469
OXYMORPHONE HYDROCHLORIDE	0.8921
PENTAZOCINE HCL	0.8867
PENTAZOCINE LACTATE	0.7601
PENTOBARBITAL CALCIUM	0.8496
PENTOBARBITAL SODIUM	0.9114
PHENAZOCINE HYDROBROMIDE	0.7989
PHENCYCLIDINE HYDROCHLORIDE(PCP-HCL)	0.8697
PHENCYCLIDINE,DEUTERATED	0.9798
PHENDINETRAZINE HYDROCHLORIDE	0.8399
PHENDIMETRAZINE TARTRATE	0.5603
PHENMETRAZINE HYDROCHLORIDE	0.8294
PHENOBARBITAL CALCIUM	0.8528
PHENOBARBITAL SODIUM	0.9136
PHENTERMINE HYDROCHLORIDE	0.8037
PHENYLPROPANOLAMINE HCL	0.8057
PIMINODINE ESYLATE	0.7689
PIMINODINE ETHANESULFONATE	0.7689
PIPERIDINE HYDROCHLORIDE	0.7002
PIPERIDINE PHOSPHATE	0.4649
PIPRADOL HYDROCHLORIDE	0.8800
PROBARBITAL CALCIUM	0.8115
PROBARBITAL SODIUM	0.9001
PROPIRAM FUMARATE	0.7035
PSEUDOMORPHINE HYDROCHLORIDE	0.9398
PYROVALERONE HYDROCHLORIDE	0.8706
RACEMORPHAN HYDROBROMIDE	0.7607
ROLICYCLIDINE HYRDOCHLORIDE(PYRROLIDINE ANALOG)	0.8692
SECOBARBITAL SODIUM	0.9155
SUFENTANIL CITRATE	0.6680
TENOCYCLIDINE HYDRO CHLORIDE(TCP-HCL),THIOPHENE ANALOG	0.8726
THEBAINE BITARTRATE	0.6494
THEBAINE HYDROCHLORIDE	0.8510
THIALBARBITAL SODIUM	0.9232
THIANYLAL SODIUM	0.9204
THIOPENTAL SODIUM	0.9167
TROPACOCAINE HYDROCHLORIDE	0.8706
VINBARBITAL SODIUM	0.9107
ZOLPIDEM BITARTRATE	0.8038

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APPENDIX 4

USE of QUANTITY, UNIT, and STRENGTH FIELDS

NDC NUMBER	PACKAGE DESCRIPTION	QUANTITY	UNIT	STRENGTH	DESCRIPTION of ITEM(S) REPORTED
12345-6789-04	4 fl oz Bottle	00000001			1 Bottle of 4 fl oz.
12345-6789-04	4 fl oz Bottle	00000015			15 Each 4 fl oz Bottles (60 fl oz).
12345-6789-04	4 fl oz Bottle	00000001		0750	1 partial Bottle of 3 fl oz (75% of 4 fl oz).
01234-0002-01	Bottle of 500 Tabs	00000002	D		2 Dozen Bottles @ 500 Tabs each (12,000 Tabs).
01234-0003-01	Bottle of 100 Caps	00000001		0900	1 Bottle of 90 Caps (90% of a Package).
01234-0003-01	Bottle of 100 Caps	00000001		1150	115.0% of 100 equals 115 Caps (one full bottle of 100 plus a partial bottle of 15) .
01234-9999-01	5ml Amp Injection	00000001			5ml Ampule.
01234-9999-01	5ml Amp Injection	00000005			5 each 5ml Ampules (25ml).
01234-9999-02	Box of 10 each 5ml Ampules (Injection)	00000001			1 box of 10 each 5ml Ampules (50ml).
01234-9999-02	Box of 10 each 5ml Ampules (Injection)	00000010			10 boxes of 10 each 5ml Ampules (500ml).
12345-0001-**	Unpackaged Bulk Tabs	00000001			1 Tab.
12345-0001-**	Unpackaged Bulk Tabs	00000001	K		1,000 Tabs.
12345-0002-**	**RAW Bulk Powder** +	00000012	3++	1000++	12gms of Bulk Powder @ 100.0% purity.
12345-0003-**	Unpackaged Bulk Liquid	00000850	5		850 ml of Bulk Liquid.
12345-0003-**	Unpackaged Bulk Liquid	00000010	6		10 liters of Bulk Liquid.
12345-0004-**	Unpackaged Bulk Beads	00000010	3		10gms of Bulk Beads (Intermediate)
12345-0004-**	Unpackaged Bulk Beads	00000001	4		4kgs of Bulk Beads (Intermediate)

NOTES: + For ARCOS transactions, the STRENGTH and UNIT fields must be completed when reporting NDC's designated as RAW Bulk in the ARCOS NDC Dictionary.
++ Mandatory Field.
UNIT Field Values: K=Thousands, D= Dozens, 1=Micrograms, 2=Milligrams, 3=Grams, 4=Kilograms, 5=Milliliters, 6=Liters

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APPENDIX 5

ARCOS RECORD: DATA FIELDS AND CALCULATIONS

NDC Pkg. Code (1)	Trans. Record Quantity Field (2)	Unit Field (3)	Strength Field (4)	Inventory Quantity (5)	Inventory Quantity X Ingredient weight (6)
Numeric or Alpha	Numeric	Blank	Numeric (Partial Pkg.)	Quantity X Pkg.% if applicable	Qty of DU's to Grams
	Numeric	Blank	Blank	Quantity	Qty of DU's to Grams
		D	Blank	Quantity x 12	Qty of DU's to Grams
		K	Blank	Quantity x 1000	Qty of DU's to Grams
**(RAW) Bulk Powder	Numeric	1	Numeric	Quantity X .000001 x Strength	Micrograms to Grams
		2	"	Quantity X .001 x Strength	Milligrams to Grams
		3	"	Quantity X Strength	Grams to Grams
		4	"	Quantity X 1000 X Strength	Kilograms to Grams
		5	"	Quantity X 1 X Strength	Milliliters to Grams
		6	"	Quantity X 1000 X Strength	Liters to Grams
** (Unpackaged, Bulk Dosage Units)	Numeric	Blank	Blank	Quantity	Qty of DU's to Grams
		D	"	Quantity X 12	Qty of DU's to Grams
		K	"	Quantity X 1000	Qty of DU's to Grams
		1	"	Quantity X .000001	Micrograms to Grams
		2	"	Quantity X .001	Milligrams to Grams
		3	"	Quantity X 1	Grams to Grams
		4	"	Quantity X 1000	Kilograms to Grams
		5	"	Quantity X 1	Milliliters to Grams
		6	"	Quantity X 1000	Liters to Grams

This chart demonstrates the procedure employed by the ARCOS system in calculating the quantity of controlled substance in a reported ARCOS transaction.

Column (1)
NDC Package Code, identifies three basic types of NDC products

Column (2)
Transaction Record Quantity Field, specifies the amount (i.e., quantity) of the NDC product involved in the ARCOS activity (i.e., transaction)

Column (3)
Unit Field, identifies specific coding designations that reflect the size (D,K); weight (1, 2, 3, 4); or volume (5, 6) associated with the reported NDC product.

Column (4)
Strength Field, reflects: (a) the purity of the controlled drug substance contained in the NDC product or (b) a percentage of the NDC product's trade package being reported.

Column (5)
Inventory Quantity, illustrates algorithms used by the ARCOS software

Column (6)
Inventory Quantity X Ingredient Weight, identifies the final gram conversion of the controlled drug substance contained in the reported NDC product by taking into account any effect of quantity, unit and strength information. The resulting figure is multiplied by the ingredient weight data of the specific NDC product involved in the reported transaction. The ingredient weight of the controlled substance in the NDC product is contained in the ARCOS drug ingredient dictionary.

KEY:
"Blank" indicates there is no entry.
DU = dosage unit (capsule, tablet, etc.)
D = Dozen
K = Thousands